

105TH CONGRESS
2D SESSION

S. 2416

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE SENATE OF THE UNITED STATES

JULY 31, 1998

Mr. CHAFEE (for himself, Mr. GRAHAM, Mr. LIEBERMAN, Mr. SPECTER, and Mr. BAUCUS) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Promoting Responsible Managed Care Act of 1998”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

- Sec. 2. Definitions.
- Sec. 3. Preemption; State flexibility; construction.
- Sec. 4. Regulations.

TITLE I—PROMOTING RESPONSIBLE MANAGED CARE

Subtitle A—Grievance and Appeals

- Sec. 101. Definitions and general provisions relating to grievance and appeals.
- Sec. 102. Utilization review activities.
- Sec. 103. Establishment of process for grievances.
- Sec. 104. Coverage determinations.
- Sec. 105. Internal appeals (reconsiderations).
- Sec. 106. External appeals (reviews).

Subtitle B—Consumer Information

- Sec. 111. Health plan information.
- Sec. 112. Health care quality information.
- Sec. 113. Confidentiality and accuracy of enrollee records.
- Sec. 114. Quality assurance.

Subtitle C—Patient Protection Standards

- Sec. 121. Emergency services.
- Sec. 122. Enrollee choice of health professionals and providers.
- Sec. 123. Access to approved services.
- Sec. 124. Nondiscrimination in delivery of services.
- Sec. 125. Prohibition of interference with certain medical communications.
- Sec. 126. Provider incentive plans.
- Sec. 127. Provider participation.
- Sec. 128. Required coverage for appropriate hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer; required coverage for reconstructive surgery following mastectomies.

Subtitle D—Enhanced Enforcement Authority

- Sec. 141. Investigations and reporting authority, injunctive relief authority, and increased civil money penalty authority for Secretary of Health and Human Services for violations of patient protection standards.
- Sec. 142. Authority for Secretary of Labor to impose civil penalties for violations of patient protection standards.

TITLE II—PATIENT PROTECTION STANDARDS UNDER THE PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

TITLE III—PATIENT PROTECTION STANDARDS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 302. Enforcement for economic loss caused by coverage determinations.

TITLE IV—PATIENT PROTECTION STANDARDS UNDER THE
INTERNAL REVENUE CODE OF 1986

Sec. 401. Amendments to the Internal Revenue Code of 1986.

TITLE V—EFFECTIVE DATES; COORDINATION IN
IMPLEMENTATION

Sec. 501. Effective dates.

Sec. 502. Coordination in implementation.

1 SEC. 2. DEFINITIONS.

2 (a) INCORPORATION OF GENERAL DEFINITIONS.—

3 The provisions of section 2971 of the Public Health Serv-
4 ice Act shall apply for purposes of this section, section
5 3, and title I in the same manner as they apply for pur-
6 poses of title XXVII of such Act.

7 (b) SECRETARY.—Except as otherwise provided, for
8 purposes of this section and title I, the term “Secretary”
9 means the Secretary of Health and Human Services, in
10 consultation with the Secretary of Labor and the Sec-
11 retary of the Treasury, and the term “appropriate Sec-
12 retary” means the Secretary of Health and Human Serv-
13 ices in relation to carrying out title I under sections 2706
14 and 2751 of the Public Health Service Act, the Secretary
15 of Labor in relation to carrying out title I under section
16 713 of the Employee Retirement Income Security Act of
17 1974, and the Secretary of the Treasury in relation to car-
18 rying out title I under chapter 100 and section 4980D
19 of the Internal Revenue Code of 1986.

1 (c) ADDITIONAL DEFINITIONS.—For purposes of this
 2 section and title I:

3 (1) APPLICABLE AUTHORITY.—The term “ap-
 4 plicable authority” means—

5 (A) in the case of a group health plan, the
 6 Secretary of Health and Human Services and
 7 the Secretary of Labor; and

8 (B) in the case of a health insurance issuer
 9 with respect to a specific provision of title I, the
 10 applicable State authority (as defined in section
 11 2791(d) of the Public Health Service Act), or
 12 the Secretary of Health and Human Services, if
 13 such Secretary is enforcing such specific provi-
 14 sion under section 2722(a)(2) or 2761(a)(2) of
 15 the Public Health Service Act.

16 (2) CLINICAL PEER.—The term “clinical peer”
 17 means, with respect to a review or appeal, a physi-
 18 cian (allopathic or osteopathic) or other health care
 19 professional who holds a non-restricted license in a
 20 State and who is appropriately credentialed, li-
 21 censed, certified, or accredited in the same or similar
 22 specialty as manages (or typically manages) the
 23 medical condition, procedure, or treatment under re-
 24 view or appeal and includes a pediatric specialist
 25 where appropriate; except that only a physician may

1 be a clinical peer with respect to the review or ap-
 2 peal of treatment rendered by a physician.

3 (3) HEALTH CARE PROVIDER.—The term
 4 “health care provider” includes a physician or other
 5 health care professional, as well as an institutional
 6 provider of health care services.

7 (4) NONPARTICIPATING.—The term “non-
 8 participating” means, with respect to a health care
 9 provider that provides health care items and services
 10 to a participant, beneficiary, or enrollee under a
 11 group health plan or health insurance coverage, a
 12 health care provider that is not a participating
 13 health care provider with respect to such items and
 14 services.

15 (5) PARTICIPATING.—The term “participating”
 16 mean, with respect to a health care provider that
 17 provides health care items and services to a partici-
 18 pant, beneficiary, or enrollee under a group health
 19 plan or health insurance coverage offered by a
 20 health insurance issuer, a health care provider that
 21 furnishes such items and services under a contract
 22 or other arrangement with the plan or issuer.

23 **SEC. 3. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.**

24 (a) CONTINUED APPLICABILITY OF STATE LAW
 25 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

1 (1) IN GENERAL.—Subject to paragraphs (2)
 2 and (3), title I shall not be construed to supersede
 3 any provision of State law which establishes, imple-
 4 ments, or continues in effect any standard or re-
 5 quirement solely relating to health insurance issuers
 6 in connection with group health insurance coverage
 7 except to the extent that such standard or require-
 8 ment prevents the application of a requirement of
 9 such title.

10 (2) CONTINUED PREEMPTION WITH RESPECT
 11 TO GROUP HEALTH PLANS.—Nothing in title I shall
 12 be construed to affect or modify the provisions of
 13 section 514 of the Employee Retirement Income Se-
 14 curity Act of 1974 with respect to group health
 15 plans.

16 (3) CONSTRUCTION WITH RESPECT TO TIME
 17 PERIODS.—Subject to paragraph (2), nothing in title
 18 I shall be construed to prohibit a State from estab-
 19 lishing, implementing, or continuing in effect any re-
 20 quirement or standard that uses a shorter period of
 21 time, than that provided under such title, for any in-
 22 ternal or external appeals process to be used by
 23 health insurance issuers.

24 (b) RULES OF CONSTRUCTION.—Nothing in title I
 25 (other than section 128) shall be construed as requiring

1 a group health plan or health insurance coverage to pro-
 2 vide specific benefits under the terms of such plan or cov-
 3 erage.

4 (c) DEFINITIONS.—For purposes of this section:

5 (1) STATE LAW.—The term “State law” in-
 6 cludes all laws, decisions, rules, regulations, or other
 7 State action having the effect of law, of any State.
 8 A law of the United States applicable only to the
 9 District of Columbia shall be treated as a State law
 10 rather than a law of the United States.

11 (2) INCLUSION OF POLITICAL SUBDIVISIONS OF
 12 A STATE.—The term “State” also includes any polit-
 13 ical subdivisions of a State or any agency or instru-
 14 mentality thereof.

15 (d) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
 16 VIDERS.—

17 (1) IN GENERAL.—Nothing in this Act (or the
 18 amendments made thereby) shall be construed to—

19 (A) restrict or limit the right of group
 20 health plans, and of health insurance issuers of-
 21 fering health insurance coverage in connection
 22 with group health plans, to include as providers
 23 religious nonmedical providers;

24 (B) require such plans or issuers to—

1 (i) utilize medically based eligibility
 2 standards or criteria in deciding provider
 3 status of religious nonmedical providers;

4 (ii) use medical professionals or cri-
 5 teria to decide patient access to religious
 6 nonmedical providers;

7 (iii) utilize medical professionals or
 8 criteria in making decisions in internal or
 9 external appeals from decisions denying or
 10 limiting coverage for care by religious non-
 11 medical providers; or

12 (iv) compel a participant or bene-
 13 ficiary to undergo a medical examination
 14 or test as a condition of receiving health
 15 insurance coverage for treatment by a reli-
 16 gious nonmedical provider; or

17 (C) require such plans or issuers to ex-
 18 clude religious nonmedical providers because
 19 they do not provide medical or other data other-
 20 wise required, if such data is inconsistent with
 21 the religious nonmedical treatment or nursing
 22 care provided by the provider.

23 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
 24 purposes of this subsection, the term “religious non-
 25 medical provider” means a provider who provides no

1 medical care but who provides only religious non-
 2 medical treatment or religious nonmedical nursing
 3 care.

4 **SEC. 4. REGULATIONS.**

5 The Secretaries of Health and Human Services,
 6 Labor, and the Treasury shall issue such regulations as
 7 may be necessary or appropriate to carry out this Act.
 8 Such regulations shall be issued consistent with section
 9 104 of Health Insurance Portability and Accountability
 10 Act of 1996. Such Secretaries may promulgate any in-
 11 terim final rules as the Secretaries determine are appro-
 12 priate to carry out this Act.

13 **TITLE I—PROMOTING**
 14 **RESPONSIBLE MANAGED CARE**
 15 **Subtitle A—Grievance and Appeals**

16 **SEC. 101. DEFINITIONS AND GENERAL PROVISIONS RELAT-**
 17 **ING TO GRIEVANCE AND APPEALS.**

18 (a) DEFINITIONS.—In this subtitle:

19 (1) AUTHORIZED REPRESENTATIVE.—The term
 20 “authorized representative” means, with respect to a
 21 covered individual, an individual who—

22 (A) is—

23 (i) any treating health care profes-
 24 sional of the covered individual (acting
 25 within the scope of the professional’s li-

1 cense or certification under applicable
2 State law), or

3 (ii) any legal representative of the
4 covered individual (or, in the case of a de-
5 ceased individual, the legal representative
6 of the estate of the individual),
7 regardless of whether such professional or rep-
8 resentative is affiliated with the plan or issuer
9 involved; and

10 (B) is acting on behalf of the covered indi-
11 vidual with the individual's consent.

12 (2) COVERAGE DETERMINATION.—The term
13 “coverage determination” means a determination by
14 a group health plan or a health insurance issuer
15 with respect to any of the following:

16 (A) A decision whether to pay for emer-
17 gency services (as defined in section
18 121(a)(2)(B)).

19 (B) A decision whether to pay for health
20 care services not described in subparagraph (A)
21 that are furnished by a provider that is a par-
22 ticipating health care provider with the plan or
23 issuer.

24 (C) A decision whether to provide benefits
25 or payment for such benefits.

1 (D) A decision whether to discontinue a
2 benefit.

3 (E) A decision resulting from the applica-
4 tion of utilization review (as defined in section
5 102(a)(1)(C)).

6 Such term includes, pursuant to section 104(d)(2), the
7 failure to provide timely notice under section 104(d).

8 (3) COVERED INDIVIDUAL.—The term “covered
9 individual” means an individual who is a participant
10 or beneficiary in a group health plan or an enrollee
11 in health insurance coverage offered by a health in-
12 surance issuer.

13 (4) GRIEVANCE.—The term “grievance” means
14 any complaint or dispute other than one involving a
15 coverage determination.

16 (5) RECONSIDERATION.—The term “reconsider-
17 ation” is defined in section 105(a)(7).

18 (6) UTILIZATION REVIEW.—The term “utiliza-
19 tion review” is defined in section 102(a)(1)(C).

20 (b) SUMMARY OF RIGHTS OF INDIVIDUALS.—In ac-
21 cordance with the provisions of this subtitle, a covered in-
22 dividual has the following rights with respect to a group
23 health plan and with respect to a health insurance issuer
24 in connection with the provision of health insurance cov-
25 erage:

1 (1) The right to have grievances between the
2 covered individual and the plan or issuer heard and
3 resolved as provided in section 103.

4 (2) The right to a timely coverage determina-
5 tion as provided in section 104.

6 (3) The right to request expedited treatment of
7 a coverage determination as provided in section
8 104(c).

9 (4) If dissatisfied with any part of a coverage
10 determination, the following appeal rights:

11 (A) The right to a timely reconsideration
12 of an adverse coverage determination as pro-
13 vided in section 105.

14 (B) The right to request expedited treat-
15 ment of such a reconsideration as provided in
16 section 105(c).

17 (C) If, as a result of a reconsideration of
18 the adverse coverage determination, the plan or
19 issuer affirms, in whole or in part, its adverse
20 coverage determination, the right to request
21 and receive a review of, and decision on, such
22 determination by a qualified external appeal en-
23 tity as provided in section 106.

24 (c) REQUIREMENTS.—

1 (1) PROCEDURES.—A group health plan, and a
 2 health insurance issuer in connection with the provi-
 3 sion of health insurance coverage shall, with respect
 4 to the provision of benefits under such plan or cov-
 5 erage—

6 (A) establish and maintain—

7 (i) grievance procedures in accordance
 8 with section 103;

9 (ii) procedures for coverage deter-
 10 minations consistent with section 104; and

11 (iii) appeals procedures for adverse
 12 coverage determinations in accordance with
 13 sections 105 and 106; and

14 (B) provide for utilization review consistent
 15 with section 102.

16 (2) DELEGATION.—A group health plan or a
 17 health insurance issuer in connection with the provi-
 18 sion of health insurance coverage that delegates any
 19 of its responsibilities under this subtitle to another
 20 entity or individual through which the plan or issuer
 21 provides health care services shall ultimately be re-
 22 sponsible for ensuring that such entity or individual
 23 satisfies the relevant requirements of this subtitle.

24 **SEC. 102. UTILIZATION REVIEW ACTIVITIES.**

25 (a) IN GENERAL.—

1 (1) COMPLIANCE WITH REQUIREMENTS.—

2 (A) IN GENERAL.—A group health plan,
3 and a health insurance issuer in connection
4 with the provision of health insurance coverage,
5 shall conduct utilization review activities in con-
6 nection with the provision of benefits under
7 such plan or coverage only in accordance with
8 a utilization review program that meets the re-
9 quirements of this section.

10 (B) USE OF OUTSIDE AGENTS.—Nothing
11 in this section shall be construed as preventing
12 a group health plan or health insurance issuer
13 from arranging through a contract or otherwise
14 for persons or entities to conduct utilization re-
15 view activities on behalf of the plan or issuer,
16 so long as such activities are conducted in ac-
17 cordance with a utilization review program that
18 meets the requirements of this section.

19 (C) UTILIZATION REVIEW DEFINED.—For
20 purposes of this section, the terms “utilization
21 review” and “utilization review activities” mean
22 procedures used to monitor or evaluate the clin-
23 ical necessity, appropriateness, efficacy, or effi-
24 ciency of health care services, procedures or set-
25 tings, and includes prospective review, concur-

1 rent review, second opinions, case management,
2 discharge planning, or retrospective review.

3 (2) WRITTEN POLICIES AND CRITERIA.—

4 (A) WRITTEN POLICIES.—A utilization re-
5 view program shall be conducted consistent with
6 written policies and procedures that govern all
7 aspects of the program.

8 (B) USE OF WRITTEN CRITERIA.—

9 (i) IN GENERAL.—Such a program
10 shall utilize written clinical review criteria
11 developed pursuant to the program with
12 the input of appropriate physicians. Such
13 criteria shall include written clinical review
14 criteria described in section 114(b)(4)(B).

15 (ii) CONTINUING USE OF STANDARDS
16 IN RETROSPECTIVE REVIEW.—If a health
17 care service has been specifically pre-au-
18 thorized or approved for a covered individ-
19 ual under such a program, the program
20 shall not, pursuant to retrospective review,
21 revise or modify the specific standards, cri-
22 teria, or procedures used for the utilization
23 review for procedures, treatment, and serv-
24 ices delivered to the individual during the
25 same course of treatment.

1 (3) CONDUCT OF PROGRAM ACTIVITIES.—

2 (A) ADMINISTRATION BY HEALTH CARE
3 PROFESSIONALS.—

4 (i) IN GENERAL.—A utilization review
5 program shall be administered by qualified
6 health care professionals who shall oversee
7 review decisions.

8 (ii) HEALTH CARE PROFESSIONAL DE-
9 FINED.—In this subsection, the term
10 “health care professional” means a physi-
11 cian or other health care practitioner li-
12 censed, accredited, or certified to perform
13 specified health services consistent with
14 State law.

15 (B) USE OF QUALIFIED, INDEPENDENT
16 PERSONNEL.—

17 (i) IN GENERAL.—A utilization review
18 program shall provide for the conduct of
19 utilization review activities only through
20 personnel who are qualified and, to the ex-
21 tent required, who have received appro-
22 priate training in the conduct of such ac-
23 tivities under the program.

24 (ii) PEER REVIEW OF SAMPLE OF AD-
25 VERSE CLINICAL DETERMINATIONS.—Such

1 a program shall provide that clinical peers
 2 (as defined in section 2(c)(2)) shall evalu-
 3 ate the clinical appropriateness of at least
 4 a sample of adverse clinical determinations.

5 (iii) PROHIBITION OF CONTINGENT
 6 COMPENSATION ARRANGEMENTS.—Such a
 7 program shall not, with respect to utiliza-
 8 tion review activities, permit or provide
 9 compensation or anything of value to its
 10 employees, agents, or contractors in a
 11 manner that—

12 (I) provides direct or indirect in-
 13 centives for such persons to make in-
 14 appropriate review decisions; or

15 (II) is based, directly or indi-
 16 rectly, on the quantity or type of ad-
 17 verse determinations rendered.

18 (iv) PROHIBITION OF CONFLICTS.—
 19 Such a program shall not permit a health
 20 care professional who provides health care
 21 services to a covered individual to perform
 22 utilization review activities in connection
 23 with the health care services being pro-
 24 vided to the individual. A group health
 25 plan, or a health insurance issuer in con-

1 nection with the provision of health insur-
2 ance coverage, may not retaliate against a
3 covered individual or health care provider
4 based on such individual's or provider's use
5 of, or participation in, the utilization re-
6 view program under this section.

7 (C) ACCESSIBILITY OF REVIEW.—Such a
8 program shall provide that appropriate person-
9 nel performing utilization review activities
10 under the program are reasonably accessible by
11 toll-free telephone during normal business hours
12 to discuss patient care and allow response to
13 telephone requests, and that appropriate provi-
14 sion is made to receive and respond promptly to
15 calls received during other hours.

16 (D) LIMITS ON FREQUENCY.—Such a pro-
17 gram shall not provide for the performance of
18 utilization review activities with respect to a
19 class of services furnished to a covered individ-
20 ual more frequently than is reasonably required
21 to assess whether the services under review are
22 medically necessary or appropriate.

23 (E) LIMITATION ON INFORMATION RE-
24 QUESTS.—Such a program shall provide that
25 information shall be required to be provided by

1 health care providers only to the extent it is
 2 necessary to perform the utilization review ac-
 3 tivity involved.

4 (F) REVIEW OF PRELIMINARY UTILIZA-
 5 TION REVIEW DECISION.—Such a program shall
 6 provide that a covered individual who is dissat-
 7 isfied with a preliminary utilization review deci-
 8 sion has the opportunity to discuss the decision
 9 with, and have such decision reviewed by, the
 10 medical director of the plan or issuer involved
 11 (or the director’s designee) who has the author-
 12 ity to reverse the decision.

13 (b) STANDARDS RELATING TO MEDICAL DECISION
 14 MAKING.—

15 (1) IN GENERAL.—In providing for a coverage
 16 determination in the process of carrying out utiliza-
 17 tion review, a group health plan, and a health insur-
 18 ance issuer in connection with the provision of
 19 health insurance coverage, may not arbitrarily inter-
 20 fere with or alter the decision of the treating physi-
 21 cian if the services are medically necessary or appro-
 22 priate for treatment or diagnosis to the extent that
 23 such treatment or diagnosis is otherwise a covered
 24 benefit.

1 (2) CONSTRUCTION.—Paragraph (1) shall not
 2 be construed as prohibiting a plan or issuer from
 3 limiting the delivery of services to one or more
 4 health care providers within a network of such pro-
 5 viders.

6 (3) NO CHANGE IN COVERAGE.—Paragraph (1)
 7 shall not be construed as requiring coverage of par-
 8 ticular services the coverage of which is otherwise
 9 not covered under the terms of the plan or coverage
 10 or from conducting utilization review activities con-
 11 sistent with this section.

12 (4) MEDICAL NECESSITY OR APPROPRIATENESS
 13 DEFINED.—In paragraph (1), the term “medically
 14 necessary or appropriate” means, with respect to a
 15 service or benefit, a service or benefit which is con-
 16 sistent with generally accepted principles of profes-
 17 sional medical practice.

18 **SEC. 103. ESTABLISHMENT OF PROCESS FOR GRIEVANCES.**

19 (a) ESTABLISHMENT.—A group health plan, and a
 20 health insurance issuer in connection with the provision
 21 of health insurance coverage, shall provide meaningful
 22 procedures for timely hearing and resolution of grievances
 23 brought by covered individuals regarding any aspect of the
 24 plan’s or issuer’s services, including a decision not to expe-

1 dite a coverage determination or reconsideration under
 2 section 104(c)(4)(B)(ii)(II) or 105(c)(4)(B)(ii)(II).

3 (b) GUIDELINES.—The grievance procedures re-
 4 quired under subsection (a) shall meet all guidelines estab-
 5 lished by the appropriate Secretary.

6 (c) DISTINGUISHED FROM COVERAGE DETERMINA-
 7 TIONS AND APPEALS.—The grievance procedures required
 8 under subsection (a) shall be separate and distinct from
 9 procedures regarding coverage determinations under sec-
 10 tion 104 and reconsiderations under section 105 and ex-
 11 ternal reviews by a qualified external appeal entity under
 12 section 106 (which address appeals of coverage determina-
 13 tions).

14 **SEC. 104. COVERAGE DETERMINATIONS.**

15 (a) REQUIREMENT.—

16 (1) RESPONSIBILITIES.—A group health plan,
 17 and a health insurance issuer in connection with the
 18 provision of health insurance coverage, shall estab-
 19 lish and maintain procedures for making timely cov-
 20 erage determinations (in accordance with the re-
 21 quirements of this section) regarding the benefits a
 22 covered individual is entitled to receive from the plan
 23 or issuer, including the amount of any copayments,
 24 deductibles, or other cost sharing applicable to such
 25 benefits. Under this section, the plan or issuer shall

1 have a standard procedure for making such deter-
2 minations, and procedures for expediting such deter-
3 minations in cases in which application of the stand-
4 ard deadlines could seriously jeopardize the covered
5 individual's life, health, or ability to regain or main-
6 tain maximum function or (in the case of a child
7 under the age of 6) development.

8 (2) PARTIES WHO MAY REQUEST COVERAGE
9 DETERMINATIONS.—Any of the following may re-
10 quest a coverage determination relating to a covered
11 individual and are parties to such determination:

12 (A) The covered individual and an author-
13 ized representative of the individual.

14 (B) A health care provider who has fur-
15 nished an item or service to the individual and
16 formally agrees to waive any right to payment
17 directly from the individual for that item or
18 service.

19 (C) Any other provider or entity (other
20 than the group health plan or health insurance
21 issuer) determined by the appropriate Secretary
22 to have an appealable interest in the determina-
23 tion.

24 (3) EFFECT OF COVERAGE DETERMINATION.—
25 A coverage determination is binding on all parties

1 unless it is reconsidered pursuant to section 105 or
2 reviewed pursuant to section 106.

3 (b) DETERMINATION BY DEADLINE.—

4 (1) IN GENERAL.—In the case of a request for
5 a coverage determination, the group health plan or
6 health insurance issuer shall provide notice pursuant
7 to subsection (d) to the person submitting the re-
8 quest of its determination as expeditiously as the
9 health condition of the covered individual involved
10 requires, but in no case later than deadline estab-
11 lished under paragraph (2) or, if a request for expe-
12 dited treatment of a coverage determination is
13 granted under subsection (c), the deadline estab-
14 lished under paragraph (3).

15 (2) STANDARD DEADLINE.—

16 (A) IN GENERAL.—The deadline estab-
17 lished under this paragraph is, subject to sub-
18 paragraph (B), 14 calendar days after the date
19 the plan or issuer receives the request for the
20 coverage determination.

21 (B) EXTENSION.—The plan or issuer may
22 extend the deadline under subparagraph (A) by
23 up to 14 calendar days if—

(i) the covered individual (or an authorized representative of the individual) requests the extension; or

(ii) the plan or issuer justifies to the applicable authority a need for additional information to make the coverage determination and how the delay is in the interest of the covered individual.

(3) EXPEDITED TREATMENT DEADLINE.—

(A) IN GENERAL.—The deadline established under this paragraph is, subject to subparagraphs (B) and (C), 72 hours after the date the plan or issuer receives the request for the expedited treatment under subsection (c).

(B) EXTENSION.—The plan or issuer may extend the deadline under subparagraph (A) by up to 5 calendar days if—

(i) the covered individual (or an authorized representative of the individual) requests the extension; or

(ii) the plan or issuer justifies to the applicable authority a need for additional information to make the coverage determination and how the delay is in the interest of the covered individual.

1 (C) HOW INFORMATION FROM NON-
 2 PARTICIPATING PROVIDERS AFFECTS DEAD-
 3 LINES FOR EXPEDITED COVERAGE DETERMINA-
 4 TIONS.—In the case of a group health plan or
 5 health insurance issuer that requires medical
 6 information from nonparticipating providers in
 7 order to make a coverage determination, the
 8 deadline specified under subparagraph (A) shall
 9 begin when the plan or issuer receives such in-
 10 formation. Nonparticipating providers shall
 11 make reasonable and diligent efforts to expedi-
 12 tiously gather and forward all necessary infor-
 13 mation to the plan or issuer in order to receive
 14 timely payment.

15 (c) EXPEDITED TREATMENT.—

16 (1) REQUEST FOR EXPEDITED TREATMENT.—A
 17 covered individual (or an authorized representative
 18 of the individual) may request that the plan or
 19 issuer expedite a coverage determination involving
 20 the issues described in subparagraphs (C), (D), or
 21 (E) of section 101(a)(2).

22 (2) WHO MAY REQUEST.—To request expedited
 23 treatment of a coverage determination, a covered in-
 24 dividual (or authorized representative of the individ-
 25 ual) shall submit an oral or written request directly

1 to the plan or issuer (or, if applicable, to the entity
2 that the plan or issuer has designated as responsible
3 for making the determination).

4 (3) PROVIDER SUPPORT.—

5 (A) IN GENERAL.—A physician or other
6 health care provider may provide oral or written
7 support for a request for expedited treatment
8 under this subsection.

9 (B) PROHIBITION OF PUNITIVE ACTION.—

10 A group health plan and a health insurance
11 issuer in connection with the provision of health
12 insurance coverage shall not take or threaten to
13 take any punitive action against a physician or
14 other health care provider acting on behalf or
15 in support of a covered individual seeking expedited treatment under this subsection.

17 (4) PROCESSING OF REQUESTS.—A group

18 health plan and a health insurance issuer in connection with the provision of health insurance coverage shall establish and maintain the following procedures for processing requests for expedited treatment of coverage determinations:

23 (A) An efficient and convenient means for
24 the submission of oral and written requests for
25 expedited treatment. The plan or issuer shall

1 document all oral requests in writing and main-
2 tain the documentation in the case file of the
3 covered individual involved.

4 (B) A means for deciding promptly wheth-
5 er to expedite a determination, based on the fol-
6 lowing requirements:

7 (i) For a request made or supported
8 by a physician, the plan or issuer shall ex-
9 pedite the coverage determination if the
10 physician indicates that applying the
11 standard deadline under subsection (b)(2)
12 for making the determination could seri-
13 ously jeopardize the covered individual's
14 life, health, or ability to regain or maintain
15 maximum function or (in the case of a
16 child under the age of 6) development.

17 (ii) For another request, the plan or
18 issuer shall expedite the coverage deter-
19 mination if the plan or issuer determines
20 that applying such standard deadline for
21 making the determination could seriously
22 jeopardize the covered individual's life,
23 health, or ability to regain or maintain
24 maximum function or (in the case of a
25 child under the age of 6) development.

1 (5) ACTIONS FOLLOWING DENIAL OF REQUEST
2 FOR EXPEDITED TREATMENT.—If a group health
3 plan or a health insurance issuer in connection with
4 the provision of health insurance coverage denies a
5 request for expedited treatment of a coverage deter-
6 mination under this subsection, the plan or issuer
7 shall—

8 (A) make the coverage determination with-
9 in the standard deadline otherwise applicable;
10 and

11 (B) provide the individual submitting the
12 request with—

13 (i) prompt oral notice of the denial of
14 the request, and

15 (ii) within 2 business days a written
16 notice that—

17 (I) explains that the plan or
18 issuer will process the coverage deter-
19 mination request within the standard
20 deadlines;

21 (II) informs the requester of the
22 right to file a grievance if the re-
23 quester disagrees with the plan's or
24 issuer's decision not to expedite the
25 determination; and

1 (III) provides instructions about
 2 the grievance process and its time-
 3 frames.

4 (6) ACTION ON ACCEPTED REQUEST FOR EXPE-
 5 DITED TREATMENT.—If a group health plan or
 6 health insurance issuer grants a request for expe-
 7 dited treatment of a coverage determination, the
 8 plan or issuer shall make the determination and pro-
 9 vide the notice under subsection (d) within the dead-
 10 lines specified under subsection (b)(3).

11 (d) NOTICE OF COVERAGE DETERMINATIONS.—

12 (1) REQUIREMENT.—

13 (A) IN GENERAL.—A group health plan or
 14 health insurance issuer that makes a coverage
 15 determination that—

16 (i) is completely favorable to the cov-
 17 ered individual shall provide the party sub-
 18 mitting the request for the coverage deter-
 19 mination with notice of such determina-
 20 tion; or

21 (ii) is adverse, in whole or in part, to
 22 the covered individual shall provide such
 23 party with written notice of the determina-
 24 tion, including the information described in
 25 subparagraph (B).

1 (B) CONTENT OF WRITTEN NOTICE.—A
2 written notice under subparagraph (A)(ii)
3 shall—

4 (i) provide the specific reasons for the
5 determination (including, in the case of a
6 determination relating to utilization review,
7 the clinical rationale for the determination)
8 in clear and understandable language;

9 (ii) include notice of the availability of
10 the clinical review criteria relied upon in
11 making the coverage determination;

12 (iii) describe the reconsideration and
13 review processes established to carry out
14 sections 105 and 106, including the right
15 to, and conditions for, obtaining expedited
16 consideration of requests for reconsider-
17 ation or review; and

18 (iv) comply with any other require-
19 ments specified by the appropriate Sec-
20 retary.

21 (2) FAILURE TO PROVIDE TIMELY NOTICE.—

22 Any failure of a group health plan or health insur-
23 ance issuer to provide a covered individual with
24 timely notice of a coverage determination as speci-
25 fied in this section shall constitute an adverse cov-

1 erage determination and a timely request for a re-
 2 consideration with respect to such determination
 3 shall be deemed to have been made pursuant to the
 4 section 105(a)(2).

5 (3) PROVISION OF ORAL NOTICE WITH WRIT-
 6 TEN CONFIRMATION IN CASE OF EXPEDITED TREAT-
 7 MENT.—If a group health plan or health insurance
 8 issuer grants a request for expedited treatment
 9 under subsection (c), the plan or issuer may first
 10 provide notice of the coverage determination orally
 11 within the deadlines established under subsection
 12 (b)(3) and then shall mail written confirmation of
 13 the determination within 2 business days of the date
 14 of oral notification.

15 **SEC. 105. INTERNAL APPEALS (RECONSIDERATIONS).**

16 (a) REQUIREMENT.—

17 (1) RESPONSIBILITIES.—A group health plan,
 18 and a health insurance issuer in connection with the
 19 provision of health insurance coverage, shall estab-
 20 lish and maintain procedures for making timely re-
 21 considerations of coverage determinations in accord-
 22 ance with this section. Under this section, the plan
 23 or issuer shall have a standard procedure for making
 24 such determinations, and procedures for expediting
 25 such determinations in cases in which application of

1 the standard deadlines could seriously jeopardize the
2 covered individual's life, health, or ability to regain
3 or maintain maximum function or (in the case of a
4 child under the age of 6) development.

5 (2) PARTIES WHO MAY REQUEST RECONSIDER-
6 ATION.—Any party to a coverage determination may
7 request a reconsideration of the determination under
8 this section. Such party shall submit an oral or writ-
9 ten request directly with the group health plan or
10 health insurance issuer that made the determination.
11 The party who files a request for reconsideration
12 may withdraw it by filing a written request for with-
13 drawal with the group health plan or health insur-
14 ance issuer involved.

15 (3) DEADLINE FOR FILING REQUEST.—

16 (A) IN GENERAL.—Except as provided in
17 subparagraph (B), a party to a coverage deter-
18 mination shall submit the request for a recon-
19 sideration within 60 calendar days from the
20 date of the written notice of the coverage deter-
21 mination.

22 (B) EXTENDING TIME FOR FILING RE-
23 QUEST.—Such a party may submit a written re-
24 quest to the plan or issuer to extend the dead-
25 line specified in subparagraph (A). If such a

1 party demonstrates in the request for the exten-
 2 sion good cause for such extension, the plan or
 3 issuer may extend the deadline.

4 (4) PARTIES TO THE RECONSIDERATION.—

5 (A) IN GENERAL.—The parties to the re-
 6 consideration are the parties to the coverage de-
 7 termination, as described in section 104(a)(2),
 8 and any other provider or entity (other than the
 9 plan or issuer) whose rights with respect to the
 10 coverage determination may be affected by the
 11 reconsideration (as determined by the entity
 12 that conducts the reconsideration).

13 (B) OPPORTUNITY TO SUBMIT EVI-
 14 DENCE.—A group health plan and a health in-
 15 surance issuer shall provide the parties to the
 16 reconsideration with a reasonable opportunity
 17 to present evidence and allegations of fact or
 18 law, related to the issue in dispute, in person as
 19 well as in writing. The plan or issuer shall in-
 20 form the parties of the conditions for submit-
 21 ting the evidence, especially any time limita-
 22 tions.

23 (5) EFFECT OF RECONSIDERATION.—A decision
 24 of a plan or issuer after reconsideration is binding

1 on all parties unless it is reviewed pursuant to sec-
2 tion 106.

3 (6) LIMITATION ON CONDUCTING RECONSIDER-
4 ATION.—In conducting the reconsideration under
5 this subsection, the following rules shall apply:

6 (A) The person or persons conducting the
7 reconsideration shall not have been involved in
8 making the underlying coverage determination
9 that is the basis for such reconsideration.

10 (B) If the issuer involved in the reconsider-
11 ation is the plan’s or issuer’s denial of coverage
12 based on a lack of medical necessity, a clinical
13 peer (as defined in section 2(c)(2)) shall make
14 the reconsidered determination.

15 (7) RECONSIDERATION DEFINED.—In this sub-
16 title, the term “reconsideration” means a review
17 under this section of a coverage determination that
18 is adverse to the covered individual involved, includ-
19 ing a review of the evidence and findings upon which
20 it was based and any other evidence the parties sub-
21 mit or the group health plan or health insurance
22 issuer obtains.

23 (b) DETERMINATION BY DEADLINE.—

24 (1) IN GENERAL.—In the case of a request for
25 a reconsideration, the group health plan or health

1 insurance issuer shall provide notice pursuant to
 2 subsection (d) to the person submitting the request
 3 of its determination as expeditiously as the health
 4 condition of the covered individual involved requires,
 5 but in no case later than the deadline established
 6 under paragraph (2) or, if a request for expedited
 7 treatment of a reconsideration is granted under sub-
 8 section (c), the deadline established under paragraph
 9 (3).

10 (2) STANDARD DEADLINE.—

11 (A) IN GENERAL.—The deadline estab-
 12 lished under this paragraph is, subject to sub-
 13 paragraph (B)—

14 (i) in the case of a reconsideration re-
 15 garding the coverage of benefits, 30 cal-
 16 endar days after the date the plan or
 17 issuer receives the request for the reconsid-
 18 eration, or

19 (ii) in other cases, 60 days after such
 20 date.

21 (B) EXTENSION.—The plan or issuer may
 22 extend the deadline under subparagraph (A) by
 23 up to 14 calendar days if—

(i) the covered individual (or an authorized representative of the individual) requests the extension; or

(ii) the plan or issuer justifies to the applicable authority a need for additional information to make the reconsideration and how the delay is in the interest of the covered individual.

(3) EXPEDITED TREATMENT DEADLINE.—

(A) IN GENERAL.—The deadline established under this paragraph is, subject to subparagraphs (B) and (C), 72 hours after the date the plan or issuer receives the request for the expedited treatment under subsection (d).

(B) EXTENSION.—The plan or issuer may extend the deadline under subparagraph (A) by up to 5 calendar days if—

(i) the covered individual (or an authorized representative of the individual) requests the extension; or

(ii) the plan or issuer justifies to the applicable authority a need for additional information to make the reconsideration and how the delay is in the interest of the covered individual.

1 (C) HOW INFORMATION FROM NON-
 2 PARTICIPATING PROVIDERS AFFECTS DEAD-
 3 LINES FOR EXPEDITED RECONSIDERATIONS.—

4 In the case of a group health plan or health in-
 5 surance issuer that requires medical informa-
 6 tion from nonparticipating providers in order to
 7 make a reconsideration, the deadline specified
 8 under subparagraph (A) shall begin when the
 9 plan or issuer receives such information. Non-
 10 participating providers shall make reasonable
 11 and diligent efforts to expeditiously gather and
 12 forward all necessary information to the plan or
 13 issuer in order to receive timely payment.

14 (c) EXPEDITED TREATMENT.—

15 (1) REQUEST FOR EXPEDITED TREATMENT.—A
 16 covered individual (or an authorized representative
 17 of the individual) may request that the plan or
 18 issuer expedite a reconsideration involving the issues
 19 described in subparagraphs (C), (D), or (E) of sec-
 20 tion 101(a)(2).

21 (2) WHO MAY REQUEST.—To request expedited
 22 treatment of a reconsideration, a covered individual
 23 (or an authorized representative of the individual)
 24 shall submit an oral or written request directly to
 25 the plan or issuer (or, if applicable, to the entity

1 that the plan or issuer has designated as responsible
2 for making the decision relating to the reconsider-
3 ation).

4 (3) PROVIDER SUPPORT.—

5 (A) IN GENERAL.—A physician or other
6 health care provider may provide oral or written
7 support for a request for expedited treatment
8 under this subsection.

9 (B) PROHIBITION OF PUNITIVE ACTION.—

10 A group health plan and a health insurance
11 issuer in connection with the provision of health
12 insurance coverage shall not take or threaten to
13 take any punitive action against a physician or
14 other health care provider acting on behalf or
15 in support of a covered individual seeking expe-
16 dited treatment under this subsection.

17 (4) PROCESSING OF REQUESTS.—A group
18 health plan and a health insurance issuer in connec-
19 tion with the provision of health insurance coverage
20 shall establish and maintain the following procedures
21 for processing requests for expedited treatment of
22 reconsiderations:

23 (A) An efficient and convenient means for
24 the submission of oral and written requests for
25 expedited treatment. The plan or issuer shall

1 document all oral requests in writing and main-
2 tain the documentation in the case file of the
3 covered individual involved.

4 (B) A means for deciding promptly wheth-
5 er to expedite a reconsideration, based on the
6 following requirements:

7 (i) For a request made or supported
8 by a physician, the plan or issuer shall ex-
9 pedite the reconsideration if the physician
10 indicates that applying the standard dead-
11 line under subsection (b)(2) for making the
12 reconsideration determination could seri-
13 ously jeopardize the covered individual's
14 life, health, or ability to regain or maintain
15 maximum function or (in the case of a
16 child under the age of 6) development.

17 (ii) For another request, the plan or
18 issuer shall expedite the reconsideration if
19 the plan or issuer determines that applying
20 such standard deadline for making the re-
21 consideration determination could seriously
22 jeopardize the covered individual's life,
23 health, or ability to regain or maintain
24 maximum function or (in the case of a
25 child under the age of 6) development.

1 (5) ACTIONS FOLLOWING DENIAL OF REQUEST
2 FOR EXPEDITED TREATMENT.—If a group health
3 plan or a health insurance issuer in connection with
4 the provision of health insurance coverage denies a
5 request for expedited treatment of a reconsideration
6 under this subsection, the plan or issuer shall—

7 (A) make the reconsideration determina-
8 tion within the standard deadline otherwise ap-
9 plicable; and

10 (B) provide the individual submitting the
11 request with—

12 (i) prompt oral notice of the denial of
13 the request, and

14 (ii) within 2 business days a written
15 notice that—

16 (I) explains that the plan or
17 issuer will process the reconsideration
18 request within the standard deadlines;

19 (II) informs the requester of the
20 right to file a grievance if the re-
21 quester disagrees with the plan's or
22 issuer's decision not to expedite the
23 reconsideration; and

1 (III) provides instructions about
2 the grievance process and its time-
3 frames.

4 (6) ACTION ON ACCEPTED REQUEST FOR EXPE-
5 DITED TREATMENT.—If a group health plan or
6 health insurance issuer grants a request for expe-
7 dited treatment of a reconsideration, the plan or
8 issuer shall make the reconsideration determination
9 and provide the notice under subsection (d) within
10 the deadlines specified under subsection (b)(3).

11 (d) NOTICE OF DECISION IN RECONSIDERATIONS.—

12 (1) REQUIREMENT.—

13 (A) IN GENERAL.—A group health plan or
14 health insurance issuer that makes a decision in
15 the reconsideration that—

16 (i) is completely favorable to the cov-
17 ered individual shall provide the party sub-
18 mitting the request for the reconsideration
19 with notice of such decision; or

20 (ii) is adverse, in whole or in part, to
21 the covered individual shall—

22 (I) provide such party with writ-
23 ten notice of the decision, including
24 the information described in subpara-
25 graph (B), and

1 (II) prepare the case file (includ-
2 ing such notice) for the covered indi-
3 vidual involved, to be available for
4 submission (if requested) under sec-
5 tion 106(a).

6 (B) CONTENT OF WRITTEN NOTICE.—The
7 written notice under subparagraph (A)(ii)(I)
8 shall—

9 (i) provide the specific reasons for the
10 decision in the reconsideration (including,
11 in the case of a decision relating to utiliza-
12 tion review, the clinical rationale for the
13 decision) in clear and understandable lan-
14 guage;

15 (ii) include notice of the availability of
16 the clinical review criteria relied upon in
17 making the decision;

18 (iii) describe the review processes es-
19 tablished to carry out sections 106, includ-
20 ing the right to, and conditions for, obtain-
21 ing expedited consideration of requests for
22 review under such section; and

23 (iv) comply with any other require-
24 ments specified by the appropriate Sec-
25 retary.

1 (2) FAILURE TO PROVIDE TIMELY NOTICE.—

2 Any failure of a group health plan or health insur-
 3 ance issuer to provide a covered individual with
 4 timely notice of a decision in a reconsideration as
 5 specified in this section shall constitute an affirma-
 6 tion of the adverse coverage determination and the
 7 plan or issuer shall submit the case file to the quali-
 8 fied external appeal entity under section 106 within
 9 24 hours of expiration of the deadline otherwise ap-
 10 plicable.

11 (3) PROVISION OF ORAL NOTICE WITH WRIT-
 12 TEN CONFIRMATION IN CASE OF EXPEDITED TREAT-

13 MENT.—If a group health plan or health insurance
 14 issuer grants a request for expedited treatment
 15 under subsection (c), the plan or issuer may first
 16 provide notice of the decision in the reconsideration
 17 orally within the deadlines established under sub-
 18 section (b)(3) and then shall mail written confirma-
 19 tion of the decision within 2 business days of the
 20 date of oral notification.

21 (4) AFFIRMATION OF AN ADVERSE COVERAGE
 22 DETERMINATION UNDER EXPEDITED TREATMENT.—

23 If, as a result of its reconsideration, the plan or
 24 issuer affirms, in whole or in part, a coverage deter-
 25 mination that is adverse to the covered individual

1 and the reconsideration received expedited treatment
 2 under subsection (c), the plan or issuer shall submit
 3 the case file (including the written notice of the deci-
 4 sion in the reconsideration) to the qualified external
 5 appeal entity as expeditiously as the covered individ-
 6 ual's health condition requires, but in no case later
 7 than within 24 hours of its affirmation. The plan or
 8 issuer shall make reasonable and diligent efforts to
 9 assist in gathering and forwarding information to
 10 the qualified external appeal entity.

11 (5) NOTIFICATION OF INDIVIDUAL.—If the plan
 12 or issuer refers the matter to an qualified external
 13 appeal entity under paragraph (2) or (4), it shall
 14 concurrently notify the individual (or an authorized
 15 representative of the individual) of that action.

16 **SEC. 106. EXTERNAL APPEALS (REVIEWS).**

17 (a) REVIEW BY QUALIFIED EXTERNAL APPEAL EN-
 18 TITY.—

19 (1) IN GENERAL.—If a qualified external appeal
 20 entity obtains a case file under section 105(d) or
 21 under paragraph (2) and determines that—

22 (A) the individual's appeal is supported by
 23 the opinion of the individual's treating physi-
 24 cian; or

25 (B) such appeal is not so supported but—

1 (i) there is a significant financial
2 amount in controversy (as defined by the
3 Secretary); or

4 (ii) the appeal involves services for the
5 diagnosis, treatment, or management of an
6 illness, disability, or condition which the
7 entity finds, in accordance with standards
8 established by the entity and approved by
9 the Secretary, constitutes a condition that
10 could seriously jeopardize the covered indi-
11 vidual's life, health, or ability to regain or
12 maintain maximum function or (in the
13 case of a child under the age of 6) develop-
14 ment;

15 the entity shall review and resolve under this section
16 any remaining issues in dispute.

17 (2) REQUEST FOR REVIEW.—

18 (A) IN GENERAL.—A party to a reconsid-
19 ered determination under section 105 that re-
20 ceives notice of an unfavorable determination
21 under section 105(d) may request a review of
22 such determination by a qualified external ap-
23 peal entity under this section.

24 (B) TIME FOR REQUEST.—To request such
25 a review, such party shall submit an oral or

1 written request directly to the plan or issuer
2 (or, if applicable, to the entity that the plan or
3 issuer has designated as responsible for making
4 the determination).

5 (C) IF REVIEW IS REQUESTED.—If a party
6 provides the plan or issuer (or such an entity)
7 with notice of a request for such review, the
8 plan or issuer (or such entity) shall submit the
9 case file to the qualified external appeal entity
10 as expeditiously as the covered individual's
11 health condition requires, but in no case later
12 than 2 business days from the date the plan or
13 issuer (or entity) receives such request. The
14 plan or issuer (or entity) shall make reasonable
15 and diligent efforts to assist in gathering and
16 forwarding information to the qualified external
17 appeal entity.

18 (3) NOTICE AND TIMING FOR REVIEW.—The
19 qualified external appeal entity shall establish and
20 apply rules for the timing and content of notices for
21 reviews under this section (including appropriate ex-
22 pedited treatment of reviews under this section) that
23 are similar to the applicable requirements for timing
24 and content of notices in the case of reconsiderations
25 under subsections (b), (c), and (d) of section 105.

1 (4) PARTIES.—The parties to the review by a
 2 qualified external appeal entity under this section
 3 shall be the same parties listed in section 105(a)(4)
 4 who qualified during the plan’s or issuer’s reconsid-
 5 eration, with the addition of the plan or issuer.

6 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS.—

7 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-
 8 PEAL ENTITY.—

9 (A) CONTRACT REQUIREMENT.—Subject to
 10 subparagraph (B), the external appeal review
 11 under this section of a determination of a plan
 12 or issuer shall be conducted under a contract
 13 between the plan or issuer and 1 or more quali-
 14 fied external appeal entities.

15 (B) ELIGIBILITY FOR DESIGNATION AS EX-
 16 TERNAL REVIEW ENTITY.—Entities eligible to
 17 conduct reviews brought under this subsection
 18 shall include—

19 (i) any State licensed or credentialed
 20 external review entity;

21 (ii) a State agency established for the
 22 purpose of conducting independent exter-
 23 nal reviews; and

1 (iii) an independent, external entity
2 that contracts with the appropriate Sec-
3 retary.

4 (C) LICENSING AND CREDENTIALING.—

5 (i) IN GENERAL.—In licensing or
6 credentialing entities described in subpara-
7 graph (B)(i), the State agent shall use li-
8 censing and certification procedures devel-
9 oped by the State in consultation with the
10 National Association of Insurance Commis-
11 sioners.

12 (ii) SPECIAL RULE.—In the case of a
13 State that—

14 (I) has not established such li-
15 censing or credentialing procedures
16 within 24 months of the date of enact-
17 ment of this Act, the State shall li-
18 cense or credential such entities in ac-
19 cordance with procedures developed by
20 the Secretary; or

21 (II) refuses to designate such en-
22 tities, the Secretary shall license or
23 credential such entities.

24 (D) QUALIFICATIONS.—An entity (which
25 may be a governmental entity) shall meet the

following requirements in order to be a qualified external appeal entity:

(i) There is no real or apparent conflict of interest that would impede the entity from conducting external appeal activities independent of the plan or issuer.

(ii) The entity conducts external appeal activities through clinical peers (as defined in section 2(c)(2)).

(iii) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (a)(3).

(iv) The entity meets such other requirements as the appropriate Secretary may impose.

(E) LIMITATION ON PLAN OR ISSUER SELECTION.—If an applicable authority permits more than 1 entity to qualify as a qualified external appeal entity with respect to a group health plan or health insurance issuer and the plan or issuer may select among such qualified entities, the applicable authority—

1 (i) shall assure that the selection proc-
 2 ess will not create any incentives for quali-
 3 fied external appeal entities to make a de-
 4 cision in a biased manner; and

5 (ii) shall implement procedures for au-
 6 diting a sample of decisions by such enti-
 7 ties to assure that no such decisions are
 8 made in a biased manner.

9 (F) OTHER TERMS AND CONDITIONS.—

10 The terms and conditions of a contract under
 11 this paragraph shall be consistent with the
 12 standards the appropriate Secretary shall estab-
 13 lish to assure that there is no real or apparent
 14 conflict of interest in the conduct of external
 15 appeal activities. Such contract shall provide
 16 that the direct costs of the process (not includ-
 17 ing costs of representation of a covered individ-
 18 ual or other party) shall be paid by the plan or
 19 issuer, and not by the covered individual.

20 (2) ELEMENTS OF PROCESS.—An external ap-
 21 peal process under this section shall be conducted
 22 consistent with standards established by the appro-
 23 priate Secretary that include at least the following:

1 (A) FAIR PROCESS; DE NOVO DETERMINA-
 2 TION.—The process shall provide for a fair, de
 3 novo determination.

4 (B) OPPORTUNITY TO SUBMIT EVIDENCE,
 5 HAVE REPRESENTATION, AND MAKE ORAL
 6 PRESENTATION.—Any party to a review under
 7 this section—

8 (i) may submit and review evidence
 9 related to the issues in dispute,

10 (ii) may use the assistance or rep-
 11 resentation of 1 or more individuals (any
 12 of whom may be an attorney), and

13 (iii) may make an oral presentation.

14 (C) PROVISION OF INFORMATION.—The
 15 plan or issuer involved shall provide timely ac-
 16 cess to all its records relating to the matter
 17 being reviewed under this section and to all pro-
 18 visions of the plan or health insurance coverage
 19 (including any coverage manual) relating to the
 20 matter.

21 (3) ADMISSIBLE EVIDENCE.—In addition to
 22 personal health and medical information supplied
 23 with respect to an individual whose claim for bene-
 24 fits has been appealed and the opinion of the indi-
 25 vidual's treating physician or health care profes-

1 sional, an external appeals entity shall take into con-
2 sideration the following evidence:

3 (A) The results of studies that meet pro-
4 fessionally recognized standards of validity and
5 replicability or that have been published in
6 peer-reviewed journals.

7 (B) The results of professional consensus
8 conferences conducted or financed in whole or
9 in part by one or more government agencies.

10 (C) Practice and treatment guidelines pre-
11 pared or financed in whole or in part by govern-
12 ment agencies.

13 (D) Government-issued coverage and treat-
14 ment policies.

15 (E) To the extent that the entity deter-
16 mines it to be free of any conflict of interest—

17 (i) the opinions of individuals who are
18 qualified as experts in one or more fields
19 of health care which are directly related to
20 the matters under appeal, and

21 (ii) the results of peer reviews con-
22 ducted by the plan or issuer involved.

23 (c) NOTICE OF DETERMINATION BY EXTERNAL AP-
24 PEAL ENTITY.—

1 (1) RESPONSIBILITY FOR THE NOTICE.—After
 2 the qualified external appeal entity has reviewed and
 3 resolved the determination that has been appealed,
 4 such entity shall mail a notice of its final decision
 5 to the parties.

6 (2) CONTENT OF THE NOTICE.—The notice de-
 7 scribed in paragraph (1) shall—

8 (A) describe the specific reasons for the
 9 entity’s decisions; and

10 (B) comply with any other requirements
 11 specified by the appropriate Secretary.

12 (d) EFFECT OF DETERMINATION.—A final decision
 13 by the qualified external appeal entity after a review of
 14 the determination that has been appealed is final and
 15 binding on the group health plan or the health insurance
 16 issuer.

17 **Subtitle B—Consumer Information**

18 **SEC. 111. HEALTH PLAN INFORMATION.**

19 (a) DISCLOSURE REQUIREMENT.—

20 (1) GROUP HEALTH PLANS.—A group health
 21 plan shall—

22 (A) provide to participants and bene-
 23 ficiaries at the time of initial coverage under
 24 the plan (or the effective date of this section, in
 25 the case of individuals who are participants or

beneficiaries as of such date), at least annually thereafter, and at the beginning of any open enrollment period provided under the plan, the information described in subsection (b) in printed form;

(B) provide to participants and beneficiaries information in printed form on material changes in the information described in paragraphs (1), (2)(A), (2)(B), (3)(A), (6), and (7) of subsection (b), or a change in the health insurance issuer through which coverage is provided, within a reasonable period of (as specified by the Secretary, but not later than 30 days after) the effective date of the changes; and

(C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsections (b) and (c) in printed form.

(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

(A) provide to individuals enrolled under such coverage at the time of enrollment, and at

1 least annually thereafter, (and to plan adminis-
2 trators of group health plans in connection with
3 which such coverage is offered) the information
4 described in subsection (b) in printed form;

5 (B) provide to enrollees and such plan ad-
6 ministrators information in printed form on
7 material changes in the information described
8 in paragraphs (1), (2)(A), (2)(B), (3)(A), (6),
9 and (7) of subsection (b), or a change in the
10 health insurance issuer through which coverage
11 is provided, within a reasonable period of (as
12 specified by the Secretary, but later than 30
13 days after) the effective date of the changes;
14 and

15 (C) upon request, make available to the
16 applicable authority, to individuals who are pro-
17 spective enrollees, to plan administrators of
18 group health plans that may obtain such cov-
19 erage, and to the public the information de-
20 scribed in subsections (b) and (c) in printed
21 form.

22 (3) EXEMPTION AUTHORITY.—Upon application
23 of one or more group health plans or health insur-
24 ance issuers, the appropriate Secretary, under proce-
25 dures established by such Secretary, may grant an

1 exemption to one or more plans or issuers from com-
 2 pliance with one or more of the requirements of
 3 paragraph (1) or (2). Such an exemption may be
 4 granted for plans and issuers as a class with similar
 5 characteristics, such as private fee-for-service plans
 6 described in section 1859(b)(2) of the Social Secu-
 7 rity Act.

8 (4) ESTABLISHMENT OF INTERNET SITE.—The
 9 appropriate Secretaries shall provide for the estab-
 10 lishment of 1 or more sites on the Internet to pro-
 11 vide technical support and information concerning
 12 the rights of participants, beneficiaries, and enrollees
 13 under this title.

14 (b) INFORMATION PROVIDED.—The information de-
 15 scribed in this subsection with respect to a group health
 16 plan or health insurance coverage offered by a health in-
 17 surance issuer includes the following:

18 (1) SERVICE AREA.—The service area of the
 19 plan or issuer.

20 (2) BENEFITS.—Benefits offered under the
 21 plan or coverage, including—

22 (A) covered benefits, including benefits for
 23 preventive services, benefit limits, and coverage
 24 exclusions, any optional supplemental benefits
 25 under the plan or coverage and the terms and

1 conditions (including premiums or cost-sharing)
2 for such supplemental benefits, and any out-of-
3 area coverage;

4 (B) cost sharing, such as premiums,
5 deductibles, coinsurance, and copayment
6 amounts, including any liability for balance bill-
7 ing, any maximum limitations on out of pocket
8 expenses, and the maximum out of pocket costs
9 for services that are provided by nonparticipat-
10 ing providers or that are furnished without
11 meeting the applicable utilization review re-
12 quirements;

13 (C) the extent to which benefits may be ob-
14 tained from nonparticipating providers, and any
15 supplemental premium or cost-sharing in so ob-
16 taining such benefits;

17 (D) the extent to which a participant, ben-
18 eficiary, or enrollee may select from among par-
19 ticipating providers and the types of providers
20 participating in the plan or issuer network;

21 (E) process for determining experimental
22 coverage or coverage in cases of investigational
23 treatments and clinical trials; and

24 (F) use of a prescription drug formulary.

25 (3) ACCESS.—A description of the following:

1 (A) The number, mix, and distribution of
2 health care providers under the plan or cov-
3 erage.

4 (B) The procedures for participants, bene-
5 ficiaries, and enrollees to select, access, and
6 change participating primary and specialty pro-
7 viders.

8 (C) The rights and procedures for obtain-
9 ing referrals (including standing referrals) to
10 participating and nonparticipating providers.

11 (D) Any limitations imposed on the selec-
12 tion of qualifying participating health care pro-
13 viders, including any limitations imposed under
14 section 122(a)(2)(B).

15 (E) How the plan or issuer addresses the
16 needs of participants, beneficiaries, and enroll-
17 ees and others who do not speak English or
18 who have other special communications needs in
19 accessing providers under the plan or coverage,
20 including the provision of information described
21 in this subsection and subsection (c) to such in-
22 dividuals, including the provision of information
23 in a language other than English if 5 percent
24 of the number of participants, beneficiaries, and
25 enrollees communicate in that language instead

1 of English, and including the availability of in-
 2 terpreters, audio tapes, and information in
 3 braille to meet the needs of people with special
 4 communications needs.

5 (4) OUT-OF-AREA COVERAGE.—Out-of-area cov-
 6 erage provided by the plan or issuer.

7 (5) EMERGENCY COVERAGE.—Coverage of
 8 emergency services, including—

9 (A) the appropriate use of emergency serv-
 10 ices, including use of the 911 telephone system
 11 or its local equivalent in emergency situations
 12 and an explanation of what constitutes an
 13 emergency situation;

14 (B) the process and procedures of the plan
 15 or issuer for obtaining emergency services; and

16 (C) the locations of (i) emergency depart-
 17 ments, and (ii) other settings, in which plan
 18 physicians and hospitals provide emergency
 19 services and post-stabilization care.

20 (6) PRIOR AUTHORIZATION RULES.—Rules re-
 21 garding prior authorization or other review require-
 22 ments that could result in noncoverage or non-
 23 payment.

24 (7) GRIEVANCE AND APPEALS PROCEDURES.—
 25 All appeal or grievance rights and procedures under

1 the plan or coverage, including the method for filing
2 grievances and the time frames and circumstances
3 for acting on grievances and appeals, the name, ad-
4 dress, and telephone number of the applicable au-
5 thority with respect to the plan or issuer, and the
6 availability of assistance through an ombudsman to
7 individuals in relation to group health plans and
8 health insurance coverage.

9 (8) QUALITY ASSURANCE.—A summary descrip-
10 tion of the data on quality indicators and measures
11 submitted under section 112(a) for the plan or
12 issuer, including a summary description of the data
13 on process and outcome satisfaction of participants,
14 beneficiaries, and enrollees (including data on indi-
15 vidual voluntary disenrollment and grievances and
16 appeals) described in section 112(b)(3)(D), and no-
17 tice that information comparing such indicators and
18 measures for different plans and issuers is available
19 through the Agency for Health Care Policy and Re-
20 search.

21 (9) SUMMARY OF PROVIDER FINANCIAL INCEN-
22 TIVES.—A summary description of the information
23 on the types of financial payment incentives (de-
24 scribed in section 1852(j)(4) of the Social Security

1 Act) provided by the plan or issuer under the cov-
2 erage.

3 (10) INFORMATION ON ISSUER.—Notice of ap-
4 propriate mailing addresses and telephone numbers
5 to be used by participants, beneficiaries, and enroll-
6 ees in seeking information or authorization for treat-
7 ment.

8 (11) INFORMATION ON LICENSURE.—Informa-
9 tion on the licensure, certification, or accreditation
10 status of the plan or issuer.

11 (12) AVAILABILITY OF TECHNICAL SUPPORT
12 AND INFORMATION.—Notice that technical support
13 and information concerning the rights of partici-
14 pants, beneficiaries, and enrollees under this title are
15 available from the Secretary of Labor (in the case
16 of group health plans) or the Secretary of Health
17 and Human Services (in the case of health insurance
18 issuers), including the telephone numbers and mail-
19 ing address of the regional offices of the appropriate
20 Secretary and the Internet address to obtain such
21 information and support.

22 (13) ADVANCE DIRECTIVES AND ORGAN DONA-
23 TION DECISIONS.—Information regarding the use of
24 advance directives and organ donation decisions
25 under the plan or coverage.

1 (14) PARTICIPATING PROVIDER LIST.—A list of
2 current participating health care providers for the
3 relevant geographic area, including the name, ad-
4 dress and telephone number of each provider.

5 (15) AVAILABILITY OF INFORMATION ON RE-
6 QUEST.—Notice that the information described in
7 subsection (c) is available upon request and how and
8 where (such as the telephone number and Internet
9 website) such information may be obtained.

10 (c) INFORMATION MADE AVAILABLE UPON RE-
11 QUEST.—The information described in this subsection is
12 the following:

13 (1) UTILIZATION REVIEW ACTIVITIES.—A de-
14 scription of procedures used and requirements (in-
15 cluding circumstances, time frames, and appeal
16 rights) under any utilization review program under
17 section 102(a), including under any drug formulary
18 program under section 123(b).

19 (2) GRIEVANCE AND APPEALS INFORMATION.—
20 Information on the number of grievances and inter-
21 nal and external appeals and on the disposition in
22 the aggregate of such matters, including information
23 on the reasons for the disposition of external appeal
24 cases.

1 (3) METHOD OF COMPENSATION.—A summary
2 description as to the method of compensation of par-
3 ticipating health care professionals and health care
4 facilities, including information on the types of fi-
5 nancial payment incentives (described in section
6 1852(j)(4) of the Social Security Act) provided by
7 the plan or issuer under the coverage and on the
8 proportion of participating health care professionals
9 who are compensated under each type of incentive
10 under the plan or coverage.

11 (4) CONFIDENTIALITY POLICIES AND PROCE-
12 DURES.—A description of the policies and proce-
13 dures established to carry out section 112.

14 (5) FORMULARY RESTRICTIONS.—A description
15 of the nature of any drug formula restrictions, in-
16 cluding the specific prescription medications in-
17 cluded in any formulary and any provisions for ob-
18 taining off-formulary medications.

19 (6) ADDITIONAL INFORMATION ON PARTICIPAT-
20 ING PROVIDERS.—For each current participating
21 health care provider described in subsection
22 (b)(14)—

23 (A) the licensure or accreditation status of
24 the provider;

1 (B) to the extent possible, an indication of
 2 whether the provider is available to accept new
 3 patients;

4 (C) in the case of medical personnel, the
 5 education, training, speciality qualifications or
 6 certification, speciality focus, affiliation ar-
 7 rangements, and specialty board certification (if
 8 any) of the provider; and

9 (D) any measures of consumer satisfaction
 10 and quality indicators for the provider.

11 (7) PERCENTAGE OF PREMIUMS USED FOR
 12 BENEFITS (LOSS-RATIOS).—In the case of health in-
 13 surance coverage only (and not with respect to group
 14 health plans that do not provide coverage through
 15 health insurance coverage), a description of the over-
 16 all loss-ratio for the coverage (as defined in accord-
 17 ance with rules established or recognized by the Sec-
 18 retary of Health and Human Services).

19 (8) QUALITY INFORMATION DEVELOPED.—
 20 Quality information on processes and outcomes de-
 21 veloped as part of an accreditation or licensure proc-
 22 ess for the plan or issuer to the extent the informa-
 23 tion is publicly available.

24 (d) FORM OF DISCLOSURE.—

1 (1) UNIFORMITY.—Information required to be
2 disclosed under this section shall be provided in ac-
3 cordance with uniform, national reporting standards
4 specified by the Secretary, after consultation with
5 applicable State authorities, so that prospective en-
6 rollees may compare the attributes of different
7 issuers and coverage offered within an area within a
8 type of coverage. Such information shall be provided
9 in an accessible format that is understandable to the
10 average participant, beneficiary, or enrollee involved.

11 (2) INFORMATION INTO HANDBOOK.—Nothing
12 in this section shall be construed as preventing a
13 group health plan or health insurance issuer from
14 making the information under subsections (b) and
15 (c) available to participants, beneficiaries, and en-
16 rollees through an enrollee handbook or similar pub-
17 lication.

18 (3) UPDATING PARTICIPATING PROVIDER IN-
19 FORMATION.—The information on participating
20 health care providers described in subsections
21 (b)(14) and (c)(6) shall be updated within such rea-
22 sonable period as determined appropriate by the
23 Secretary. A group health plan or health insurance
24 issuer shall be considered to have complied with the
25 provisions of such subsection if the plan or issuer

1 provides the directory or listing of participating pro-
2 viders to participants and beneficiaries or enrollees
3 once a year and such directory or listing is updated
4 within such a reasonable period to reflect any mate-
5 rial changes in participating providers. Nothing in
6 this section shall prevent a plan or issuer from
7 changing or updating other information made avail-
8 able under this section.

9 (4) RULE OF MAILING TO LAST ADDRESS.—For
10 purposes of this section, a plan or issuer, in reliance
11 on records maintained by the plan or issuer, shall be
12 deemed to have met the requirements of this section
13 with respect to the disclosure of information to a
14 participant, beneficiary, or enrollee if the plan or
15 issuer transmits the information requested to the
16 participant, beneficiary, or enrollee at the address
17 contained in such records with respect to such par-
18 ticipant, beneficiary, or enrollee.

19 (e) ENROLLEE ASSISTANCE.—

20 (1) IN GENERAL.—Each State that obtains a
21 grant under paragraph (3) shall provide for creation
22 and operation of a Health Insurance Ombudsman
23 through a contract with a not-for-profit organization
24 that operates independent of group health plans and

1 health insurance issuers. Such Ombudsman shall be
2 responsible for at least the following:

3 (A) To provide consumers in the State
4 with information about health insurance cov-
5 erage options or coverage options offered within
6 group health plan.

7 (B) To provide counseling and assistance
8 to enrollees dissatisfied with their treatment by
9 health insurance issuers and group health plans
10 in regard to such coverage or plans and with re-
11 spect to grievances and appeals regarding deter-
12 minations under such coverage or plans.

13 (2) FEDERAL ROLE.—In the case of any State
14 that does not provide for such an Ombudsman under
15 paragraph (1), the Secretary may provide for the
16 creation and operation of a Health Insurance Om-
17 budsman through a contract with a not-for-profit or-
18 ganization that operates independent of group health
19 plans and health insurance issuers and that is to
20 provide consumers in the State with information
21 about health insurance coverage options or coverage
22 options offered within group health plans.

23 (3) ELIGIBILITY.—To be eligible to serve as a
24 Health Insurance Ombudsman under this section, a

1 not-for-profit organization shall provide assurances
2 that—

3 (A) the organization has no real or per-
4 ceived conflict of interest in providing advice
5 and assistance to consumers regarding health
6 insurance coverage, and

7 (B) the organization is independent of
8 health insurance issuers, health care providers,
9 health care payors, and regulators of health
10 care or health insurance.

11 (4) AUTHORIZATION OF APPROPRIATIONS.—
12 There are authorized to be appropriated to the Sec-
13 retary of Health and Human Services such amounts
14 as may be necessary to provide for grants to States
15 for contracts for Health Insurance Ombudsmen
16 under paragraph (1) or contracts for such Ombuds-
17 men under paragraph (2).

18 (5) CONSTRUCTION.—Nothing in this section
19 shall be construed to prevent the use of other forms
20 of enrollee assistance.

21 (f) CONSTRUCTION.—Nothing in this section shall be
22 construed as requiring public disclosure of individual con-
23 tracts or financial arrangements between a group health
24 plan or health insurance issuer and any provider.

1 **SEC. 112. HEALTH CARE QUALITY INFORMATION.**

2 (a) COLLECTION AND SUBMISSION OF INFORMATION
3 ON QUALITY INDICATORS AND MEASURES.—

4 (1) IN GENERAL.—A group health plan and a
5 health insurance issuer that offers health insurance
6 coverage shall collect and submit to the Director for
7 the Agency for Health Care Policy and Research (in
8 this section referred to as the “Director”) aggregate
9 data on quality indicators and measures (as defined
10 in subsection (g)) that includes the minimum uni-
11 form data set specified under subsection (b). Such
12 data shall not include patient identifiers.

13 (2) DATA SAMPLING METHODS.—The Director
14 shall develop data sampling methods for the collec-
15 tion of data under this subsection.

16 (3) EXEMPTION AUTHORITY.—The provisions
17 of section 111(a)(3) shall apply to the requirements
18 of paragraph (1) in the same manner as they apply
19 to the requirements referred to in such section.

20 (b) MINIMUM UNIFORM DATA SET.—

21 (1) IN GENERAL.—The Secretary shall specify
22 (and may from time to time update) by rule the data
23 required to be included in the minimum uniform
24 data set under subsection (a) and the standard for-
25 mat for such data.

26 (2) DESIGN.—Such specification shall—

1 (A) take into consideration the different
2 populations served (such as children and indi-
3 viduals with disabilities);

4 (B) be consistent where appropriate with
5 requirements applicable to Medicare+Choice
6 health plans under 1851(d)(4)(D) of the Social
7 Security Act;

8 (C) take into consideration such dif-
9 ferences in the delivery system among group
10 health plans and health insurance issuers as the
11 Secretary deems appropriate;

12 (D) be consistent with standards adopted
13 to carry out part C of title XI of the Social Se-
14 curity Act; and

15 (E) be consistent where feasible with exist-
16 ing health plan quality indicators and measures
17 used by employers and purchasers.

18 (3) MINIMUM DATA.—The data in such set
19 shall include, to the extent determined feasible by
20 the appropriate Secretary, at least—

21 (A) data on process measures of clinical
22 performance for health care services provided
23 by health care professionals and facilities;

24 (B) data on outcomes measures of morbid-
25 ity and mortality including to the extent fea-

1 sible and appropriate data for pediatric and
2 gender-specific measures; and

3 (C) data on data on satisfaction of such in-
4 dividuals, including data on voluntary
5 disenrollment and grievances.

6 The minimum data set under this paragraph shall
7 be established by the appropriate Secretaries using
8 a negotiated rulemaking process under subchapter
9 III of chapter 5 of title 5, United States Code.

10 (c) DISSEMINATION OF INFORMATION.—

11 (1) IN GENERAL.—The Director shall publicly
12 disseminate (through printed media and the Inter-
13 net) information on the aggregate data submitted
14 under this section.

15 (2) FORMATS.—The information shall be dis-
16 seminated in a manner that provides for a compari-
17 son of health care quality among different group
18 health plans and health insurance issuers, with ap-
19 propriate differentiation by delivery system. In dis-
20 seminating the information, the Director may ref-
21 erence an appropriate benchmark (or benchmarks)
22 for performance with respect to specific quality indi-
23 cators and measures (or groups of such measures).

24 (d) HEALTH CARE QUALITY RESEARCH AND INFOR-
25 MATION.—The Secretary of Health and Human Services,

1 acting through the Director, shall conduct and support re-
 2 search demonstration projects, evaluations, and the dis-
 3 semination of information with respect to measurement,
 4 status, improvement, and presentation of quality indica-
 5 tors and measures and other health care quality informa-
 6 tion.

7 (e) NATIONAL REPORTS ON HEALTH CARE QUAL-
 8 ITY.—

9 (1) REPORT ON NATIONAL GOALS.—Not later
 10 than 18 months after the date of enactment of this
 11 Act, and every 2 years thereafter, the Secretary of
 12 Health and Human Services shall prepare and sub-
 13 mit to the appropriate committees of Congress and
 14 the President a report that—

15 (A) establishes national goals for the im-
 16 provement of the quality of health care; and

17 (B) contains recommendations for achiev-
 18 ing the national goals established under para-
 19 graph (1).

20 (2) REPORT ON HEALTH RELATED TOPICS.—

21 Not later than 30 months after the date of enact-
 22 ment of this Act and every 2 years thereafter, such
 23 Secretary shall prepare and submit to Congress and
 24 the President a report that addresses at least 1 of
 25 the following (or a related matter):

1 (A) The availability, applicability, and ap-
 2 propriateness of information to consumers re-
 3 garding the quality of their health care.

4 (B) The state of information systems and
 5 data collecting capabilities for measuring and
 6 reporting on quality indicators.

7 (C) The impact of quality measurement on
 8 access to and the cost of medical care.

9 (D) Barriers to continuous quality im-
 10 provement in medical care.

11 (E) The state of health care quality meas-
 12 urement research and development.

13 (f) AUTHORIZATION OF APPROPRIATIONS.—There
 14 are authorized to be appropriated \$25,000,000 for each
 15 fiscal year (beginning with fiscal year 1999) to carry out
 16 this section. Any such amounts appropriated for a fiscal
 17 year shall remain available, without fiscal year limitation,
 18 until expended.

19 (g) QUALITY INDICATORS AND MEASURES DE-
 20 FINED.—For purposes of this section, the term “quality
 21 indicators and measures” means structural characteris-
 22 tics, patient-encounter data, and the subsequent health
 23 status change of a patient as a result of health care serv-
 24 ices provided by health care professionals and facilities.

1 **SEC. 113. CONFIDENTIALITY AND ACCURACY OF ENROLLEE**

2 **RECORDS.**

3 A group health plan or a health insurance issuer shall
4 establish procedures with respect to medical records or
5 other health information maintained regarding partici-
6 pants, beneficiaries, and enrollees to safeguard the privacy
7 of any individually identifiable information about them.

8 **SEC. 114. QUALITY ASSURANCE.**

9 (a) **REQUIREMENT.**—A group health plan, and a
10 health insurance issuer that offers health insurance cov-
11 erage, shall establish and maintain an ongoing, internal
12 quality assurance and continuous quality improvement
13 program that meets the requirements of subsection (b).

14 (b) **PROGRAM REQUIREMENTS.**—The requirements of
15 this subsection for a quality improvement program of a
16 plan or issuer are as follows:

17 (1) **ADMINISTRATION.**—The plan or issuer has
18 an identifiable unit with responsibility for adminis-
19 tration of the program.

20 (2) **WRITTEN PLAN.**—The plan or issuer has a
21 written plan for the program that is updated annu-
22 ally and that specifies at least the following:

23 (A) The activities to be conducted.

24 (B) The organizational structure.

25 (C) The duties of the medical director.

1 (D) Criteria and procedures for the assess-
2 ment of quality.

3 (3) SYSTEMATIC REVIEW.—The program pro-
4 vides for systematic review of the type of health
5 services provided, consistency of services provided
6 with good medical practice, and patient outcomes.

7 (4) QUALITY CRITERIA.—The program—

8 (A) uses criteria that are based on per-
9 formance and patient outcomes where feasible
10 and appropriate;

11 (B) includes criteria that are directed spe-
12 cifically at meeting the needs of at-risk popu-
13 lations and covered individuals with chronic
14 conditions or severe illnesses, including gender-
15 specific criteria and pediatric-specific criteria
16 where available and appropriate;

17 (C) includes methods for informing covered
18 individuals of the benefit of preventive care and
19 what specific benefits with respect to preventive
20 care are covered under the plan or coverage;
21 and

22 (D) makes available to the public a de-
23 scription of the criteria used under subpara-
24 graph (A).

1 (5) SYSTEM FOR IDENTIFYING.—The program
2 has procedures for identifying possible quality con-
3 cerns by providers and enrollees and for remedial ac-
4 tions to correct quality problems, including written
5 procedures for responding to concerns and taking
6 appropriate corrective action.

7 (6) DATA ANALYSIS.—The program provides,
8 using data that include the data collected under sec-
9 tion 112, for an analysis of the plan’s or issuer’s
10 performance on quality measures.

11 (7) DRUG UTILIZATION REVIEW.—The program
12 provides for a drug utilization review program
13 which—

14 (A) encourages appropriate use of prescrip-
15 tion drugs by participants, beneficiaries, and
16 enrollees and providers, and

17 (B) takes appropriate action to reduce the
18 incidence of improper drug use and adverse
19 drug reactions and interactions.

20 (c) DEEMING.—For purposes of subsection (a), the
21 requirements of—

22 (1) subsection (b) (other than paragraph (5))
23 are deemed to be met with respect to a health insur-
24 ance issuer that is a qualified health maintenance

1 organization (as defined in section 1310(c) of the
2 Public Health Service Act); or

3 (2) subsection (b) are deemed to be met with
4 respect to a health insurance issuer that is accred-
5 ited by a national accreditation organization that the
6 Secretary certifies as applying, as a condition of cer-
7 tification, standards at least as stringent as those re-
8 quired for a quality improvement program under
9 subsection (b).

10 (d) VARIATION PERMITTED.—The Secretary may
11 provide for variations in the application of the require-
12 ments of this section to group health plans and health in-
13 surance issuers based upon differences in the delivery sys-
14 tem among such plans and issuers as the Secretary deems
15 appropriate.

16 (e) CONSULTATION IN MEDICAL POLICIES.—A group
17 health plan, and health insurance issuer that offers health
18 insurance coverage, shall consult with participating physi-
19 cians (if any) regarding the plan’s or issuer’s medical pol-
20 icy, quality, and medical management procedures.

21 **Subtitle C—Patient Protection** 22 **Standards**

23 **SEC. 121. EMERGENCY SERVICES.**

24 (a) COVERAGE OF EMERGENCY SERVICES.—

1 (1) IN GENERAL.—If a group health plan, or
2 health insurance coverage offered by a health insur-
3 ance issuer, provides any benefits with respect to
4 emergency services (as defined in paragraph (2)(B)),
5 the plan or issuer shall cover emergency services fur-
6 nished under the plan or coverage—

7 (A) without the need for any prior author-
8 ization determination;

9 (B) whether or not the health care pro-
10 vider furnishing such services is a participating
11 provider with respect to such services;

12 (C) in a manner so that, if such services
13 are provided to a participant, beneficiary, or en-
14 rollee by a nonparticipating health care pro-
15 vider—

16 (i) the participant, beneficiary, or en-
17 rollee is not liable for amounts that exceed
18 the amounts of liability that would be in-
19 curred if the services were provided by a
20 participating health care provider, and

21 (ii) the plan or issuer pays an amount
22 that is not less than the amount paid to a
23 participating health care provider for the
24 same services; and

(D) without regard to any other term or condition of such plan or coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—The term “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term “emergency services” means—

1 (i) a medical screening examination
2 (as required under section 1867 of the So-
3 cial Security Act) that is within the capa-
4 bility of the emergency department of a
5 hospital, including ancillary services rou-
6 tinely available to the emergency depart-
7 ment to evaluate an emergency medical
8 condition (as defined in subparagraph
9 (A)), and

10 (ii) within the capabilities of the staff
11 and facilities available at the hospital, such
12 further medical examination and treatment
13 as are required under section 1867 of such
14 Act to stabilize the patient.

15 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND
16 POST-STABILIZATION CARE.—In the case of services
17 (other than emergency services) for which benefits are
18 available under a group health plan, or under health insur-
19 ance coverage offered by a health insurance issuer, the
20 plan or issuer shall provide for reimbursement with re-
21 spect to such services provided to a participant, bene-
22 ficiary, or enrollee other than through a participating
23 health care provider in a manner consistent with sub-
24 section (a)(1)(C) if the services are maintenance care or
25 post-stabilization care covered under the guidelines estab-

1 lished under section 1852(d)(2) of the Social Security Act
 2 (relating to promoting efficient and timely coordination of
 3 appropriate maintenance and post-stabilization care of an
 4 enrollee after an enrollee has been determined to be sta-
 5 ble), in accordance with regulations established to carry
 6 out such section.

7 **SEC. 122. ENROLLEE CHOICE OF HEALTH PROFESSIONALS**
 8 **AND PROVIDERS.**

9 (a) CHOICE OF PERSONAL HEALTH PROFES-
 10 SIONAL.—

11 (1) PRIMARY CARE.—A group health plan, and
 12 a health insurance issuer that offers health insur-
 13 ance coverage, shall permit each participant, bene-
 14 ficiary, and enrollee—

15 (A) to receive primary care from any par-
 16 ticipating primary care provider who is avail-
 17 able to accept such individual, and

18 (B) in the case of a participant, bene-
 19 ficiary, or enrollee who has a child who is also
 20 covered under the plan or coverage, to des-
 21 ignate a participating physician who specializes
 22 in pediatrics as the child's primary care pro-
 23 vider.

24 (2) SPECIALISTS.—

(A) IN GENERAL.—Subject to subparagraph (B), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care.

(B) LIMITATION.—Subparagraph (A) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating providers with respect to such care.

(b) SPECIALIZED SERVICES.—

(1) OBSTETRICAL AND GYNECOLOGICAL CARE.—

(A) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider, and an individual who is female has not designated a participating physician

specializing in obstetrics and gynecology as a
primary care provider, the plan or issuer—

(i) may not require authorization or a
referral by the individual's primary care
provider or otherwise for coverage of rou-
tine gynecological care (such as preventive
women's health examinations) and preg-
nancy-related services provided by a par-
ticipating health care professional who spe-
cializes in obstetrics and gynecology to the
extent such care is otherwise covered, and

(ii) may treat the ordering of other
gynecological care by such a participating
physician as the authorization of the pri-
mary care provider with respect to such
care under the plan or coverage.

(B) CONSTRUCTION.—Nothing in subpara-
graph (A)(ii) shall waive any requirements of
coverage relating to medical necessity or appro-
priateness with respect to coverage of gyneco-
logical care so ordered.

(2) SPECIALTY CARE.—

(A) SPECIALTY CARE FOR COVERED SERV-
ICES.—

(i) IN GENERAL.—If—

1 (I) an individual is a participant
2 or beneficiary under a group health
3 plan or an enrollee who is covered
4 under health insurance coverage of-
5 fered by a health insurance issuer,

6 (II) the individual has a condi-
7 tion or disease of sufficient serious-
8 ness and complexity to require treat-
9 ment by a specialist, and

10 (III) benefits for such treatment
11 are provided under the plan or cov-
12 erage,

13 the plan or issuer shall make or provide for
14 a referral to a specialist who is available
15 and accessible to provide the treatment for
16 such condition or disease.

17 (ii) SPECIALIST DEFINED.—For pur-
18 poses of this paragraph, the term “special-
19 ist” means, with respect to a condition, a
20 health care practitioner, facility, or center
21 (such as a center of excellence) that has
22 adequate expertise through appropriate
23 training and experience (including, in the
24 case of a child, appropriate pediatric exper-

1 tise) to provide high quality care in treat-
2 ing the condition.

3 (iii) CARE UNDER REFERRAL.—A
4 group health plan or health insurance
5 issuer may require that the care provided
6 to an individual pursuant to such referral
7 under clause (i) be—

8 (I) pursuant to a treatment plan,
9 only if the treatment plan is developed
10 by the specialist and approved by the
11 plan or issuer, in consultation with
12 the designated primary care provider
13 or specialist and the individual (or the
14 individual's designee), and

15 (II) in accordance with applicable
16 quality assurance and utilization re-
17 view standards of the plan or issuer.

18 Nothing in this paragraph shall be con-
19 strued as preventing such a treatment plan
20 for an individual from requiring a special-
21 ist to provide the primary care provider
22 with regular updates on the specialty care
23 provided, as well as all necessary medical
24 information.

1 (iv) REFERRALS TO PARTICIPATING
 2 PROVIDERS.—A group health plan or
 3 health insurance issuer is not required
 4 under clause (i) to provide for a referral to
 5 a specialist that is not a participating pro-
 6 vider, unless the plan or issuer does not
 7 have an appropriate specialist that is avail-
 8 able and accessible to treat the individual's
 9 condition and that is a participating pro-
 10 vider with respect to such treatment.

11 (v) TREATMENT OF NONPARTICIPAT-
 12 ING PROVIDERS.—If a plan or issuer refers
 13 an individual to a nonparticipating special-
 14 ist pursuant to clause (i), services provided
 15 pursuant to the approved treatment plan
 16 (if any) shall be provided at no additional
 17 cost to the individual beyond what the indi-
 18 vidual would otherwise pay for services re-
 19 ceived by such a specialist that is a partici-
 20 pating provider.

21 (B) SPECIALISTS AS PRIMARY CARE PRO-
 22 VIDERS.—

23 (i) IN GENERAL.—A group health
 24 plan, or a health insurance issuer, in con-
 25 nection with the provision of health insur-

ance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in clause (iii)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care. If such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(ii) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in subparagraph (A)(iii)(I)).

(iii) ONGOING SPECIAL CONDITION DEFINED.—In this subparagraph, the term

“special condition” means a condition or disease that—

(I) is life-threatening, degenerative, or disabling, and

(II) requires specialized medical care over a prolonged period of time.

(iv) TERMS OF REFERRAL.—The provisions of clauses (iii) through (v) of subparagraph (A) apply with respect to referrals under clause (i) of this subparagraph in the same manner as they apply to referrals under subparagraph (A)(i).

(C) STANDING REFERRALS.—

(i) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer

1 and the specialist (if any), determines that
 2 such a standing referral is appropriate, the
 3 plan or issuer shall make such a referral to
 4 such a specialist.

5 (ii) TERMS OF REFERRAL.—The pro-
 6 visions of clauses (iii) through (v) of sub-
 7 paragraph (A) apply with respect to refer-
 8 rals under clause (i) of this subparagraph
 9 in the same manner as they apply to refer-
 10 rals under subparagraph (A)(i).

11 (c) CONTINUITY OF CARE.—

12 (1) IN GENERAL.—

13 (A) TERMINATION OF PROVIDER.—If a
 14 contract between a group health plan, or a
 15 health insurance issuer in connection with the
 16 provision of health insurance coverage, and a
 17 health care provider is terminated (as defined
 18 in subparagraph (C)), or benefits or coverage
 19 provided by a health care provider are termi-
 20 nated because of a change in the terms of pro-
 21 vider participation in a group health plan, and
 22 an individual who is a participant, beneficiary,
 23 or enrollee in the plan or coverage is under-
 24 going a course of treatment from the provider

1 at the time of such termination, the plan or
2 issuer shall—

3 (i) notify the individual on a timely
4 basis of such termination, and

5 (ii) subject to paragraph (3), permit
6 the individual to continue or be covered
7 with respect to the course of treatment
8 with the provider during a transitional pe-
9 riod (provided under paragraph (2)) if the
10 plan or issuer is notified orally or in writ-
11 ing of the facts and circumstances concern-
12 ing the course of treatment.

13 (B) TREATMENT OF TERMINATION OF
14 CONTRACT WITH HEALTH INSURANCE
15 ISSUER.—If a contract for the provision of
16 health insurance coverage between a group
17 health plan and a health insurance issuer is ter-
18 minated and, as a result of such termination,
19 coverage of services of a health care provider is
20 terminated with respect to an individual, the
21 provisions of subparagraph (A) (and the suc-
22 ceeding provisions of this section) shall apply
23 under the group health plan in the same man-
24 ner as if there had been a direct contract be-
25 tween the group health plan and the provider

1 that had been terminated, but only with respect
 2 to benefits that are covered under the group
 3 health plan after the contract termination.

4 (C) TERMINATION.—In this section, the
 5 term “terminated” includes, with respect to a
 6 contract, the expiration or nonrenewal of the
 7 contract, but does not include a termination of
 8 the contract by the plan or issuer for failure to
 9 meet applicable quality standards or for fraud.

10 (2) TRANSITIONAL PERIOD.—

11 (A) IN GENERAL.—Except as provided in
 12 subparagraphs (B) through (D), the transi-
 13 tional period under this subsection shall extend
 14 for at least 90 days from the date of the notice
 15 described in paragraph (1)(A)(i) of the provid-
 16 er’s termination.

17 (B) INSTITUTIONAL CARE.—The transi-
 18 tional period under this subsection for institu-
 19 tional or inpatient care from a provider shall
 20 extend until the discharge or termination of the
 21 period of institutionalization and also shall in-
 22 clude institutional care provided within a rea-
 23 sonable time of the date of termination of the
 24 provider status.

25 (C) PREGNANCY.—If—

1 (i) a participant, beneficiary, or en-
 2 rollee has entered the second trimester of
 3 pregnancy at the time of a provider's ter-
 4 mination of participation, and

5 (ii) the provider was treating the
 6 pregnancy before date of the termination,
 7 the transitional period under this subsection
 8 with respect to provider's treatment of the
 9 pregnancy shall extend through the provision of
 10 post-partum care directly related to the deliv-
 11 ery.

12 (D) TERMINAL ILLNESS.—If—

13 (i) a participant, beneficiary, or en-
 14 rollee was determined to be terminally ill
 15 (as determined under section
 16 1861(dd)(3)(A) of the Social Security Act)
 17 at the time of a provider's termination of
 18 participation, and

19 (ii) the provider was treating the ter-
 20 minal illness before the date of termi-
 21 nation,

22 the transitional period under this subsection
 23 shall extend for the remainder of the individ-
 24 ual's life for care directly related to the treat-
 25 ment of the terminal illness, but in no case is

1 the transitional period required to extend for
2 longer than 180 days.

3 (3) PERMISSIBLE TERMS AND CONDITIONS.—A
4 group health plan or health insurance issuer may
5 condition coverage of continued treatment by a pro-
6 vider under paragraph (1)(A)(ii) upon the provider
7 agreeing to the following terms and conditions:

8 (A) The provider agrees to accept reim-
9 bursement from the plan or issuer and individ-
10 ual involved (with respect to cost-sharing) at
11 the rates applicable prior to the start of the
12 transitional period as payment in full (or, in the
13 case described in paragraph (1)(B), at the rates
14 applicable under the replacement plan or issuer
15 after the date of the termination of the contract
16 with the health insurance issuer) and not to im-
17 pose cost-sharing with respect to the individual
18 in an amount that would exceed the cost-shar-
19 ing that could have been imposed if the contract
20 referred to in paragraph (1)(A) had not been
21 terminated.

22 (B) The provider agrees to adhere to the
23 quality assurance standards of the plan or
24 issuer responsible for payment under subpara-
25 graph (A) and to provide to such plan or issuer

1 necessary medical information related to the
2 care provided.

3 (C) The provider agrees otherwise to ad-
4 here to such plan's or issuer's policies and pro-
5 cedures, including procedures regarding utiliza-
6 tion review and referrals, and obtaining prior
7 authorization and providing services pursuant
8 to a treatment plan (if any) approved by the
9 plan or issuer.

10 (4) CONSTRUCTION.—Nothing in this sub-
11 section shall be construed to require the coverage of
12 benefits which would not have been covered if the
13 provider involved remained a participating provider.

14 (d) PROTECTION AGAINST INVOLUNTARY
15 DISENROLLMENT BASED ON CERTAIN CONDITIONS.—

16 (1) IN GENERAL.—Subject to paragraph (2), a
17 group health plan and a health insurance issuer in
18 connection with the provision of health insurance
19 coverage may not disenroll an individual under the
20 plan or coverage because the individual's behavior is
21 considered disruptive, unruly, abusive, or uncoopera-
22 tive to the extent that the individual's continued en-
23 rollment under the coverage seriously impairs the
24 plan's or issuer's ability to furnish covered services
25 if the circumstances for the individual's behavior is

1 directly related to diminished mental capacity, severe
2 and persistent mental illness, or a serious childhood
3 mental and emotional disorder.

4 (2) EXCEPTION.—Paragraph (1) shall not
5 apply if the behavior engaged in directly threatens
6 bodily injury to any person.

7 (e) GENERAL ACCESS.—

8 (1) IN GENERAL.—Each group health plan, and
9 each health insurance issuer offering health insur-
10 ance coverage, that provides benefits, in whole or in
11 part, through participating health care providers
12 shall have (in relation to the coverage) a sufficient
13 number, distribution, and variety of qualified partici-
14 pating health care providers to ensure that all cov-
15 ered health care services, including specialty serv-
16 ices, will be available and accessible in a timely man-
17 ner to all participants, beneficiaries, and enrollees
18 under the plan or coverage.

19 (2) TREATMENT OF CERTAIN PROVIDERS.—The
20 qualified health care providers under paragraph (1)
21 may include Federally qualified health centers, rural
22 health clinics, migrant health centers, high-volume,
23 disproportionate share hospitals, and other essential
24 community providers located in the service area of
25 the plan or issuer and shall include such providers

1 if necessary to meet the standards established to
 2 carry out such subsection.

3 **SEC. 123. ACCESS TO APPROVED SERVICES.**

4 (a) COVERAGE FOR INDIVIDUALS PARTICIPATING IN
 5 APPROVED CLINICAL TRIALS.—

6 (1) COVERAGE.—

7 (A) IN GENERAL.—If a group health plan,
 8 or health insurance issuer that is providing
 9 health insurance coverage, provides coverage to
 10 a qualified individual (as defined in paragraph
 11 (2)), the plan or issuer—

12 (i) may not deny the individual par-
 13 ticipation in the clinical trial referred to in
 14 paragraph (2)(B);

15 (ii) subject to paragraph (3), may not
 16 deny (or limit or impose additional condi-
 17 tions on) the coverage of routine patient
 18 costs for items and services furnished in
 19 connection with participation in the trial;
 20 and

21 (iii) may not discriminate against the
 22 individual on the basis of the enrollee's
 23 participation in such trial.

24 (B) EXCLUSION OF CERTAIN COSTS.—For
 25 purposes of subparagraph (A)(ii), routine pa-

1 tient costs do not include the cost of the tests
2 or measurements conducted primarily for the
3 purpose of the clinical trial involved.

4 (C) USE OF IN-NETWORK PROVIDERS.—If
5 one or more participating providers is partici-
6 pating in a clinical trial, nothing in subpara-
7 graph (A) shall be construed as preventing a
8 plan or issuer from requiring that a qualified
9 individual participate in the trial through such
10 a participating provider if the provider will ac-
11 cept the individual as a participant in the trial.

12 (2) QUALIFIED INDIVIDUAL DEFINED.—For
13 purposes of paragraph (1), the term “qualified indi-
14 vidual” means an individual who is a participant or
15 beneficiary in a group health plan, or who is an en-
16 rollee under health insurance coverage, and who
17 meets the following conditions:

18 (A)(i) The individual has a life-threatening
19 or serious illness for which no standard treat-
20 ment is effective.

21 (ii) The individual is eligible to participate
22 in an approved clinical trial according to the
23 trial protocol with respect to treatment of such
24 illness.

1 (iii) The individual's participation in the
2 trial offers meaningful potential for significant
3 clinical benefit for the individual.

4 (B) Either—

5 (i) the referring physician is a partici-
6 pating health care professional and has
7 concluded that the individual's participa-
8 tion in such trial would be appropriate
9 based upon the individual meeting the con-
10 ditions described in subparagraph (A); or

11 (ii) the participant, beneficiary, or en-
12 rollee provides medical and scientific infor-
13 mation establishing that the individual's
14 participation in such trial would be appro-
15 priate based upon the individual meeting
16 the conditions described in subparagraph
17 (A).

18 (3) PAYMENT.—

19 (A) IN GENERAL.—Under this subsection a
20 group health plan or health insurance issuer
21 shall provide for payment for routine patient
22 costs described in paragraph (1)(A) but is not
23 required to pay for costs of items and services
24 that are reasonably expected (as determined by

1 the Secretary) to be paid for by the sponsors of
2 an approved clinical trial.

3 (B) PAYMENT RATE.—In the case of cov-
4 ered items and services provided by—

5 (i) a participating provider, the pay-
6 ment rate shall be at the agreed upon rate,
7 or

8 (ii) a nonparticipating provider, the
9 payment rate shall be at the rate the plan
10 or issuer would normally pay for com-
11 parable services under subparagraph (A).

12 (4) APPROVED CLINICAL TRIAL DEFINED.—

13 (A) IN GENERAL.—In this subsection, the
14 term “approved clinical trial” means a clinical
15 research study or clinical investigation approved
16 and funded (which may include funding through
17 in-kind contributions) by one or more of the fol-
18 lowing:

19 (i) The National Institutes of Health.

20 (ii) A cooperative group or center of
21 the National Institutes of Health.

22 (iii) Either of the following if the con-
23 ditions described in subparagraph (B) are
24 met:

1 (I) The Department of Veterans
2 Affairs.

3 (II) The Department of Defense.

4 (B) CONDITIONS FOR DEPARTMENTS.—

5 The conditions described in this subparagraph,
6 for a study or investigation conducted by a De-
7 partment, are that the study or investigation
8 has been reviewed and approved through a sys-
9 tem of peer review that the Secretary deter-
10 mines—

11 (i) to be comparable to the system of
12 peer review of studies and investigations
13 used by the National Institutes of Health,
14 and

15 (ii) assures unbiased review of the
16 highest scientific standards by qualified in-
17 dividuals who have no interest in the out-
18 come of the review.

19 (5) CONSTRUCTION.—Nothing in this sub-
20 section shall be construed to limit a plan's or
21 issuer's coverage with respect to clinical trials.

22 (b) ACCESS TO PRESCRIPTION DRUGS.—

23 (1) IN GENERAL.—If a group health plan, or
24 health insurance issuer that offers health insurance
25 coverage, provides benefits with respect to prescrip-

1 tion drugs but the coverage limits such benefits to
2 drugs included in a formulary, the plan or issuer
3 shall—

4 (A) ensure participation of participating
5 physicians and pharmacists in the development
6 of the formulary; and

7 (B) disclose to providers and, disclose upon
8 request under section 111(c)(5) to participants,
9 beneficiaries, and enrollees, the nature of the
10 formulary restrictions; and

11 (C) consistent with the standards for a uti-
12 lization review program under section 102(a),
13 provide for exceptions from the formulary limi-
14 tation when a non-formulary alternative is
15 medically indicated.

16 (2) CONSTRUCTION.—Nothing in this sub-
17 section shall be construed as requiring a group
18 health plan (or health insurance issuer in connection
19 with health insurance coverage) to provide any cov-
20 erage of prescription drugs or as preventing such a
21 plan or issuer from negotiating higher cost-sharing
22 in the case a non-formulary alternative is provided
23 under paragraph (1)(C).

1 **SEC. 124. NONDISCRIMINATION IN DELIVERY OF SERVICES.**

2 (a) APPLICATION TO DELIVERY OF SERVICES.—Sub-
3 ject to subsection (b), a group health plan, and health in-
4 surance issuer in relation to health insurance coverage,
5 may not discriminate against a participant, beneficiary, or
6 enrollee in the delivery of health care services consistent
7 with the benefits covered under the plan or coverage or
8 as required by law based on race, color, ethnicity, national
9 origin, religion, sex, age, mental or physical disability, sex-
10 ual orientation, genetic information, or source of payment.

11 (b) CONSTRUCTION.—Nothing in subsection (a) shall
12 be construed as relating to the eligibility to be covered,
13 or the offering (or guaranteeing the offer) of coverage,
14 under a plan or health insurance coverage, the application
15 of any pre-existing condition exclusion consistent with ap-
16 plicable law, or premiums charged under such plan or cov-
17 erage. To the extent that health care providers are per-
18 mitted under State and Federal law to prioritize the ad-
19 mission or treatment of patients based on such patients’
20 individual religious affiliation, group health plans and
21 health insurance issuers may reflect those priorities in re-
22 ferring patients to such providers.

23 **SEC. 125. PROHIBITION OF INTERFERENCE WITH CERTAIN**
24 **MEDICAL COMMUNICATIONS.**

25 (a) IN GENERAL.—An organization on behalf of a
26 group health plan (as described in subsection (a)(2)) or

1 a health insurance issuer shall not penalize (financially or
 2 otherwise) a health care professional for advocating on be-
 3 half of his or her patient or for providing information or
 4 referral for medical care (as defined in section 2791(a)(2)
 5 of the Public Health Service Act) consistent with the
 6 health care needs of the patient and with the code of ethi-
 7 cal conduct, professional responsibility, conscience, medi-
 8 cal knowledge, and license of the health care professional.

9 (b) CONSTRUCTION.—Nothing in subsection (a) shall
 10 be construed as requiring a health insurance issuer or a
 11 group health plan to pay for medical care not otherwise
 12 paid for or covered by the plan provided by nonparticipat-
 13 ing health care professionals, except in those instances and
 14 to the extent that the issuer or plan would normally pay
 15 for such medical care.

16 (c) ASSISTANCE AND SUPPORT.—A group health plan
 17 or a health insurance issuer shall not prohibit or otherwise
 18 restrict a health care professional from providing letters
 19 of support to, or in any way assisting, enrollees who are
 20 appealing a denial, termination, or reduction of service in
 21 accordance with the procedures under subtitle A.

22 **SEC. 126. PROVIDER INCENTIVE PLANS.**

23 (a) PROHIBITION OF TRANSFER OF INDEMNIFICA-
 24 TION.—

1 (1) IN GENERAL.—No contract or agreement
 2 between a group health plan or health insurance
 3 issuer (or any agent acting on behalf of such a plan
 4 or issuer) and a health care provider shall contain
 5 any provision purporting to transfer to the health
 6 care provider by indemnification or otherwise any li-
 7 ability relating to activities, actions, or omissions of
 8 the plan, issuer, or agent (as opposed to the pro-
 9 vider).

10 (2) NULLIFICATION.—Any contract or agree-
 11 ment provision described in paragraph (1) shall be
 12 null and void.

13 (b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-
 14 TIVE PLANS.—

15 (1) IN GENERAL.—A group health plan and a
 16 health insurance issuer offering health insurance
 17 coverage may not operate any physician incentive
 18 plan (as defined in subparagraph (B) of section
 19 1876(i)(8) of the Social Security Act) unless the re-
 20 quirements described in subparagraph (A) of such
 21 section are met with respect to such a plan.

22 (2) APPLICATION.—For purposes of carrying
 23 out paragraph (1), any reference in section
 24 1876(i)(8) of the Social Security Act to the Sec-
 25 retary, an eligible organization, or an individual en-

1 rolled with the organization shall be treated as a ref-
2 erence to the applicable authority, a group health
3 plan or health insurance issuer, respectively, and a
4 participant, beneficiary, or enrollee with the plan or
5 organization, respectively.

6 **SEC. 127. PROVIDER PARTICIPATION.**

7 (a) IN GENERAL.—A group health plan and a health
8 insurance issuer that offers health insurance coverage
9 shall, if it provides benefits through participating health
10 care professionals, have a written process for the selection
11 of participating health care professionals under the plan
12 or coverage. Such process shall include—

- 13 (1) minimum professional requirements;
- 14 (2) providing notice of the rules regarding par-
15 ticipation;
- 16 (3) providing written notice of participation de-
17 cisions that are adverse to professionals; and
- 18 (4) providing a process within the plan or issuer
19 for appealing such adverse decisions, including the
20 presentation of information and views of the profes-
21 sional regarding such decision.

22 (b) VERIFICATION OF BACKGROUND.—Such process
23 shall include verification of a health care provider's license
24 and a history of suspension or revocation.

1 (c) RESTRICTION.—Such process shall not use a
2 high-risk patient base or location of a provider in an area
3 with residents with poorer health status as a basis for ex-
4 cluding providers from participation.

5 (d) GENERAL NONDISCRIMINATION.—

6 (1) IN GENERAL.—Subject to paragraph (2),
7 such process shall not discriminate with respect to
8 selection of a health care professional to be a partici-
9 pating health care provider, or with respect to the
10 terms and conditions of such participation, based on
11 the professional's race, color, religion, sex, national
12 origin, age, sexual orientation, or disability (consist-
13 ent with the Americans with Disabilities Act of
14 1990).

15 (2) RULES.—The appropriate Secretary may
16 establish such definitions, rules, and exceptions as
17 may be appropriate to carry out paragraph (1), tak-
18 ing into account comparable definitions, rules, and
19 exceptions in effect under employment-based non-
20 discrimination laws and regulations that relate to
21 each of the particular bases for discrimination de-
22 scribed in such paragraph.

1 **SEC. 128. REQUIRED COVERAGE FOR APPROPRIATE HOS-**
2 **PITAL STAY FOR MASTECTOMIES AND LYMPH**
3 **NODE DISSECTIONS FOR THE TREATMENT OF**
4 **BREAST CANCER; REQUIRED COVERAGE FOR**
5 **RECONSTRUCTIVE SURGERY FOLLOWING**
6 **MASTECTOMIES.**

7 (a) COVERAGE OF INPATIENT CARE FOR SURGICAL
8 TREATMENT OF BREAST CANCER.—

9 (1) IN GENERAL.—A group health plan, and a
10 health insurance issuer providing health insurance
11 coverage, that provides medical and surgical benefits
12 shall ensure that inpatient coverage with respect to
13 the surgical treatment of breast cancer (including a
14 mastectomy, lumpectomy, or lymph node dissection
15 for the treatment of breast cancer) is provided for
16 a period of time as is determined by the attending
17 physician, in his or her professional judgment con-
18 sistent with generally accepted principles of profes-
19 sional medical practice, in consultation with the pa-
20 tient, to be medically necessary or appropriate.

21 (2) EXCEPTION.—Nothing in this section shall
22 be construed as requiring the provision of inpatient
23 coverage if the attending physician in consultation
24 with the patient determine that a shorter period of
25 hospital stay is medically necessary or appropriate.

1 (b) COVERAGE OF RECONSTRUCTIVE SURGERY FOL-
 2 LOWING MASTECTOMIES.—A group health plan, and a
 3 health insurance issuer providing health insurance cov-
 4 erage, that provides medical and surgical benefits with re-
 5 spect to a mastectomy shall ensure that, in a case in which
 6 a mastectomy patient elects breast reconstruction, cov-
 7 erage is provided for—

8 (1) all stages of reconstruction of the breast on
 9 which the mastectomy has been performed;

10 (2) surgery and reconstruction of the other
 11 breast to produce a symmetrical appearance; and

12 (3) the costs of prostheses and complications of
 13 mastectomy including lymphedemas;

14 in the manner determined by the attending physician and
 15 the patient to be appropriate. Such coverage may be sub-
 16 ject to annual deductibles and coinsurance provisions as
 17 may be deemed appropriate and as are consistent with
 18 those established for other benefits under the plan or cov-
 19 erage. Written notice of the availability of such coverage
 20 shall be delivered to the participant or enrollee upon en-
 21 rollment and annually thereafter.

22 (c) NO AUTHORIZATION REQUIRED.—

23 (1) IN GENERAL.—An attending physician shall
 24 not be required to obtain authorization from the
 25 plan or issuer for prescribing any length of stay in

1 connection with a mastectomy, a lumpectomy, or a
2 lymph node dissection for the treatment of breast
3 cancer.

4 (2) PRENOTIFICATION.—Nothing in this section
5 shall be construed as preventing a group health plan
6 or health insurance issuer from requiring
7 prenotification of an inpatient stay referred to in
8 this section if such requirement is consistent with
9 terms and conditions applicable to other inpatient
10 benefits under the plan or health insurance coverage,
11 except that the provision of such inpatient stay bene-
12 fits shall not be contingent upon such notification.

13 (d) PROHIBITIONS.—A group health plan and a
14 health insurance issuer offering health insurance coverage
15 may not—

16 (1) deny to a patient eligibility, or continued
17 eligibility, to enroll or to renew coverage under the
18 terms of the plan or coverage, solely for the purpose
19 of avoiding the requirements of this section;

20 (2) provide monetary payments or rebates to in-
21 dividuals to encourage such individuals to accept less
22 than the minimum protections available under this
23 section;

24 (3) penalize or otherwise reduce or limit the re-
25 imbursement of an attending provider because such

1 provider provided care to an individual participant,
 2 beneficiary, or enrollee in accordance with this sec-
 3 tion;

4 (4) provide incentives (monetary or otherwise)
 5 to an attending provider to induce such provider to
 6 provide care to an individual participant, beneficiary,
 7 or enrollee in a manner inconsistent with this sec-
 8 tion; and

9 (5) subject to subsection (e)(2), restrict benefits
 10 for any portion of a period within a hospital length
 11 of stay required under subsection (a) in a manner
 12 which is less favorable than the benefits provided for
 13 any preceding portion of such stay.

14 (e) RULES OF CONSTRUCTION.—

15 (1) IN GENERAL.—Nothing in this section shall
 16 be construed to require a patient who is a partici-
 17 pant, beneficiary, or enrollee—

18 (A) to undergo a mastectomy or lymph
 19 node dissection in a hospital; or

20 (B) to stay in the hospital for a fixed pe-
 21 riod of time following a mastectomy or lymph
 22 node dissection.

23 (2) COST SHARING.—Nothing in this section
 24 shall be construed as preventing a group health plan
 25 or issuer from imposing deductibles, coinsurance, or

1 other cost-sharing in relation to benefits for hospital
 2 lengths of stay in connection with a mastectomy or
 3 lymph node dissection for the treatment of breast
 4 cancer under the plan or health insurance coverage,
 5 except that such coinsurance or other cost-sharing
 6 for any portion of a period within a hospital length
 7 of stay required under subsection (a) may not be
 8 greater than such coinsurance or cost-sharing for
 9 any preceding portion of such stay.

10 (3) LEVEL AND TYPE OF REIMBURSEMENTS.—

11 Nothing in this section shall be construed to prevent
 12 a group health plan or a health insurance issuer
 13 from negotiating the level and type of reimburse-
 14 ment with a provider for care provided in accordance
 15 with this section.

16 **Subtitle D—Enhanced Enforcement** 17 **Authority**

18 **SEC. 141. INVESTIGATIONS AND REPORTING AUTHORITY,**
 19 **INJUNCTIVE RELIEF AUTHORITY, AND IN-**
 20 **CREASED CIVIL MONEY PENALTY AUTHORITY**
 21 **FOR SECRETARY OF HEALTH AND HUMAN**
 22 **SERVICES FOR VIOLATIONS OF PATIENT PRO-**
 23 **TECTION STANDARDS.**

24 (a) INVESTIGATIONS AND REPORTING AUTHORITY.—

1 (1) IN GENERAL.—For purposes of carrying out
2 sections 2722(b) and 2761(b) of the Public Health
3 Service Act with respect to enforcement of the provi-
4 sions of sections 2706 and 2752, respectively, of
5 such Act (as added by title II of this Act)—

6 (A) the Secretary of Health and Human
7 Services shall have the same authorities with
8 respect to compelling health insurance issuers
9 to produce information and to conducting inves-
10 tigations in cases of violations of such provi-
11 sions as the Secretary of Labor has under sec-
12 tion 504 of the Employee Retirement Income
13 Security Act of 1974 with respect to violations
14 of title I of such Act; and

15 (B) section 504(c) of the Employee Retire-
16 ment Income Security Act of 1974 shall apply
17 to investigations conducted under paragraph (1)
18 in the same manner as it applies to investiga-
19 tions conducted under title I of such Act.

20 (2) REPORTING AUTHORITY.—In exercising au-
21 thority under paragraph (1), the Secretary may re-
22 quire—

23 (A) States that have indicated an intention
24 to assume authority under section 2722(a)(1)
25 or 2761(a) of the Public Health Service Act to

1 report to the Secretary on enforcement efforts
 2 undertaken to assure compliance with the re-
 3 quirements of sections 2706 and 2752, respec-
 4 tively, of such Act; and

5 (B) health insurance issuers to submit re-
 6 ports to assure compliance with such require-
 7 ments.

8 (b) AUTHORITY FOR INJUNCTIVE RELIEF.—In addi-
 9 tion to the authority referred to in subsection (a), the Sec-
 10 retary of Health and Human Services has the same au-
 11 thority with respect to enforcement of the provisions of
 12 this title as the Secretary of Labor has under subsection
 13 (a)(5) of section 502 of the Employee Retirement Income
 14 Security Act of 1974 (as applied without regard to sub-
 15 section (b) of that section) and the related provisions of
 16 part 5 of subtitle B of title I of such Act with respect
 17 to enforcement of such title I of such Act.

18 (c) INCREASE IN CIVIL MONEY PENALTIES.—

19 (1) IN GENERAL.—In the case of a civil money
 20 penalty that may be imposed under section
 21 2722(b)(2) or 2761(b) of the Public Health Service
 22 Act with respect to a failure to meet the provisions
 23 of sections 2706 and 2752, respectively, of such Act,
 24 the maximum amount of penalty otherwise provided
 25 under section 2722(b)(2)(C)(i) of such Act may, not-

1 withstanding the amounts specified in such section,
2 and subject to paragraph (2), be up to the greatest
3 of the following:

4 (A) FAILURES INVOLVING UNREASONABLE
5 DENIAL OR DELAY IN BENEFITS IMPACTING ON
6 LIFE OR HEALTH.—In the case of a failure that
7 results in an unreasonable denial or delay in
8 benefits that has seriously jeopardized (or has
9 substantial likelihood of seriously jeopardizing)
10 the individual's life, health, or ability to regain
11 or maintain maximum function or (in the case
12 of a child under the age of 6) development, the
13 greater of the following:—

14 (i) PATTERN OR PRACTICE FAIL-
15 URE.—If the failure reflects a pattern or
16 practice of wrongful conduct, \$250,000,
17 plus the amount (if any) determined under
18 paragraph (2).

19 (ii) OTHER FAILURES.—In the case of
20 a failure that does not reflect a pattern or
21 practice of wrongful conduct, \$50,000 for
22 each individual involved, plus the amount
23 (if any) determined under paragraph (2).

1 (B) OTHER FAILURES.—In the case of a
 2 failure not described in subparagraph (A), the
 3 greater of the following:

4 (i) PATTERN AND PRACTICE FAIL-
 5 URES.—In the case of a failure that re-
 6 flects a pattern or practice of wrongful
 7 conduct \$50,000, plus the amount (if any)
 8 determined under paragraph (2).

9 (ii) OTHER FAILURES.—In the case of
 10 a failure that does not reflect a pattern or
 11 practice of wrongful conduct, \$10,000 for
 12 each individual involved, plus the amount
 13 (if any) determined under paragraph (2).

14 (2) CONTINUING FAILURE WITHOUT CORREC-
 15 TION.—In the case of a failure which is not cor-
 16 rected within the first week beginning with the date
 17 on which the failure is established, the maximum
 18 amount of the penalty under paragraph (1) shall be
 19 increased by \$10,000 for each full succeeding week
 20 in which the failure is not so corrected.

21 (d) AUTHORIZATION OF APPROPRIATIONS.—In addi-
 22 tion to any other amounts authorized to be appropriated,
 23 there are authorized to be appropriated to the Secretary
 24 of Health and Human Services such sums as may be nec-
 25 essary to carry out this section.

1 **SEC. 142. AUTHORITY FOR SECRETARY OF LABOR TO IM-**
2 **POSE CIVIL PENALTIES FOR VIOLATIONS OF**
3 **PATIENT PROTECTION STANDARDS.**

4 (a) IN GENERAL.—Section 502(c) of the Employee
5 Retirement Income Security Act of 1974 (29 U.S.C.
6 1132(c)) is amended by redesignating paragraphs (6) and
7 (7) as paragraphs (7) and (8), respectively, and by insert-
8 ing after paragraph (5) the following new paragraph:

9 “(6)(A) The Secretary may assess a civil penalty
10 against a person acting in the capacity of a fiduciary of
11 a group health plan (as defined in 733(a)) so as to cause
12 a violation of section 713.

13 “(B) Subject to subparagraph (C), the maximum
14 amount which may be assessed under subparagraph (A)
15 is the greatest of the following:

16 “(i) In the case of a failure that results in an
17 unreasonable denial or delay in benefits that seri-
18 ously jeopardized (or has substantial likelihood of se-
19 riously jeopardizing) the individual’s life, health, or
20 ability to regain or maintain maximum function or
21 (in the case of a child under the age of 6) develop-
22 ment, the greater of the following:

23 “(I) If the failure reflects a pattern or
24 practice of wrongful conduct, \$250,000, plus
25 the amount (if any) determined under subpara-
26 graph (C).

1 “(II) In the case of a failure that does not
 2 reflect a pattern or practice of wrongful con-
 3 duct, \$50,000 for each individual involved, plus
 4 the amount (if any) determined under subpara-
 5 graph (C).

6 “(ii) In the case of a failure not described in
 7 clause (i), the greater of the following:

8 “(I) In the case of a failure that reflects
 9 a pattern or practice of wrongful conduct
 10 \$50,000, plus the amount (if any) determined
 11 under subparagraph (C).

12 “(II) In the case of a failure that does not
 13 reflect a pattern or practice of wrongful con-
 14 duct, \$10,000 for each individual involved, plus
 15 the amount (if any) determined under subpara-
 16 graph (C).

17 “(C) In the case of a failure which is not corrected
 18 within the first week beginning with the date on which
 19 the failure is established, the maximum amount of the
 20 penalty under subparagraph (B) shall be increased by
 21 \$10,000 for each full succeeding week in which the failure
 22 is not so corrected.”.

23 (b) CONFORMING AMENDMENT.—Section 502(a)(6)
 24 of such Act (29 U.S.C. 1132(a)(6)) is amended by striking

1 “paragraph (2), (4), (5), or (6)” and inserting “paragraph
2 (2), (4), (5), (6), or (7)”.

3 (c) AUTHORIZATION OF APPROPRIATIONS.—In addi-
4 tion to any other amounts authorized to be appropriated,
5 there are authorized to be appropriated to the Secretary
6 of Labor such sums as may be necessary to carry out the
7 amendments made by this section.

8 **TITLE II—PATIENT PROTECTION** 9 **STANDARDS UNDER PUBLIC** 10 **HEALTH SERVICE ACT**

11 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND** 12 **GROUP HEALTH INSURANCE COVERAGE.**

13 (a) IN GENERAL.—Subpart 2 of part A of title
14 XXVII of the Public Health Service Act is amended by
15 adding at the end the following new section:

16 **“SEC. 2706. PATIENT PROTECTION STANDARDS.**

17 “(a) IN GENERAL.—Each group health plan shall
18 comply with patient protection requirements under title I
19 of the Promoting Responsible Managed Care Act of 1998,
20 and each health insurance issuer shall comply with patient
21 protection requirements under such title with respect to
22 group health insurance coverage it offers, and such re-
23 quirements shall be deemed to be incorporated into this
24 subsection.

1 “(b) NOTICE.—A group health plan shall comply with
 2 the notice requirement under section 711(d) of the Em-
 3 ployee Retirement Income Security Act of 1974 with re-
 4 spect to the requirements referred to in subsection (a) and
 5 a health insurance issuer shall comply with such notice
 6 requirement as if such section applied to such issuer and
 7 such issuer were a group health plan.”.

8 (b) CONFORMING AMENDMENT.—Section
 9 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
 10 is amended by inserting “(other than section 2706)” after
 11 “requirements of such subparts”.

12 (c) REFERENCE TO ENHANCED ENFORCEMENT AU-
 13 THORITY.—For provisions providing for enhanced author-
 14 ity to enforce the patient protection requirements of title
 15 I under the Public Health Service Act, see section 141.

16 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
 17 **ANCE COVERAGE.**

18 Part B of title XXVII of the Public Health Service
 19 Act is amended by inserting after section 2751 the follow-
 20 ing new section:

21 **“SEC. 2752. PATIENT PROTECTION STANDARDS.**

22 “(a) IN GENERAL.—Each health insurance issuer
 23 shall comply with patient protection requirements under
 24 title I of the Promoting Responsible Managed Care Act
 25 of 1998 with respect to individual health insurance cov-

1 erage it offers, and such requirements shall be deemed to
 2 be incorporated into this subsection.

3 “(b) NOTICE.—A health insurance issuer under this
 4 part shall comply with the notice requirement under sec-
 5 tion 711(d) of the Employee Retirement Income Security
 6 Act of 1974 with respect to the requirements of such title
 7 as if such section applied to such issuer and such issuer
 8 were a group health plan.”.

9 **TITLE III—PATIENT PROTEC-**
 10 **TION STANDARDS UNDER**
 11 **THE EMPLOYEE RETIREMENT**
 12 **INCOME SECURITY ACT OF**
 13 **1974**

14 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
 15 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 16 **HEALTH INSURANCE COVERAGE UNDER THE**
 17 **EMPLOYEE RETIREMENT INCOME SECURITY**
 18 **ACT OF 1974.**

19 (a) IN GENERAL.—Subpart B of part 7 of subtitle
 20 B of title I of the Employee Retirement Income Security
 21 Act of 1974 is amended by adding at the end the following
 22 new section:

23 **“SEC. 713. PATIENT PROTECTION STANDARDS.**

24 “(a) IN GENERAL.—Subject to subsection (b), a
 25 group health plan (and a health insurance issuer offering

1 group health insurance coverage in connection with such
 2 a plan) shall comply with the requirements of title I of
 3 the Promoting Responsible Managed Care Act of 1998 (as
 4 in effect as of the date of the enactment of such Act),
 5 and such requirements shall be deemed to be incorporated
 6 into this subsection.

7 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
 8 MENTS.—

9 “(1) SATISFACTION OF CERTAIN REQUIRE-
 10 MENTS THROUGH INSURANCE.—For purposes of
 11 subsection (a), insofar as a group health plan pro-
 12 vides benefits in the form of health insurance cov-
 13 erage through a health insurance issuer, the plan
 14 shall be treated as meeting the following require-
 15 ments of title I of the Promoting Responsible Man-
 16 aged Care Act of 1998 with respect to such benefits
 17 and not be considered as failing to meet such re-
 18 quirements because of a failure of the issuer to meet
 19 such requirements so long as the plan sponsor or its
 20 representatives did not cause such failure by the
 21 issuer:

22 “(A) Section 121 (relating to access to
 23 emergency care).

24 “(B) Section 122 (relating to choice of
 25 providers).

1 “(C) Section 122(b) (relating to specialized
2 services).

3 “(D) Section 122(c)(1)(A) (relating to con-
4 tinuity in case of termination of provider con-
5 tract) and section 122(c)(1)(B) (relating to
6 continuity in case of termination of issuer con-
7 tract), but only insofar as a replacement issuer
8 assumes the obligation for continuity of care.

9 “(E) Section 123(a) (relating to coverage
10 for individuals participating in approved clinical
11 trials.)

12 “(F) Section 123(b) (relating to access to
13 needed prescription drugs).

14 “(G) Section 122(e) (relating to adequacy
15 of provider network).

16 “(H) Subtitle B (relating to consumer in-
17 formation).

18 “(2) INFORMATION.—With respect to informa-
19 tion required to be provided or made available under
20 section 111 of such Act, in the case of a group
21 health plan that provides benefits in the form of
22 health insurance coverage through a health insur-
23 ance issuer, the Secretary shall determine the cir-
24 cumstances under which the plan is not required to
25 provide or make available the information (and is

1 not liable for the issuer’s failure to provide or make
2 available the information), if the issuer is obligated
3 to provide and make available (or provides and
4 makes available) such information.

5 “(3) GRIEVANCE AND INTERNAL APPEALS.—

6 With respect to the grievance system and internal
7 appeals process required to be established under sec-
8 tions 102 and 103 of such Act, in the case of a
9 group health plan that provides benefits in the form
10 of health insurance coverage through a health insur-
11 ance issuer, the Secretary shall determine the cir-
12 cumstances under which the plan is not required to
13 provide for such system and process (and is not lia-
14 ble for the issuer’s failure to provide for such system
15 and process), if the issuer is obligated to provide for
16 (and provides for) such system and process.

17 “(4) EXTERNAL APPEALS.—Pursuant to rules
18 of the Secretary, insofar as a group health plan en-
19 ters into a contract with a qualified external appeal
20 entity for the conduct of external appeal activities in
21 accordance with section 106 of such Act, the plan
22 shall be treated as meeting the requirement of such
23 section and is not liable for the entity’s failure to
24 meet any requirements under such section.

1 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
 2 ant to rules of the Secretary, if a health insurance
 3 issuer offers health insurance coverage in connection
 4 with a group health plan and takes an action in vio-
 5 lation of any of the following sections of such Act,
 6 the group health plan shall not be liable for such
 7 violation unless the plan caused such violation:

8 “(A) Section 124 (relating to non-
 9 discrimination in delivery of services).

10 “(B) Section 125 (relating to prohibition
 11 of interference with certain medical communica-
 12 tions).

13 “(C) Section 126 (relating to provider in-
 14 centive plans).

15 “(D) Section 102(b) (relating to providing
 16 medically necessary care).

17 “(6) CONSTRUCTION.—Nothing in this sub-
 18 section shall be construed to affect or modify the re-
 19 sponsibilities of the fiduciaries of a group health
 20 plan under part 4 of subtitle B.

21 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE
 22 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
 23 1133) is amended by inserting “(a)” after “SEC. 503.”
 24 and by adding at the end the following new subsection:

1 “(b) In the case of a group health plan (as defined
 2 in section 733) compliance with the requirements of sub-
 3 title D (and section 113) of title I of the Promoting Re-
 4 sponsible Managed Care Act of 1998 in the case of a
 5 claims denial shall be deemed compliance with subsection
 6 (a) with respect to such claims denial.”.

7 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)
 8 of such Act (29 U.S.C. 1185(a)) is amended by striking
 9 “section 711” and inserting “sections 711 and 713”.

10 (2) The table of contents in section 1 of such Act
 11 is amended by inserting after the item relating to section
 12 712 the following new item:

“Sec. 713. Patient protection standards.”.

13 (3) Section 502(b)(3) of such Act (29 U.S.C.
 14 1132(b)(3)) is amended by inserting “(other than section
 15 144(b))” after “part 7”.

16 (d) REFERENCE TO ENHANCED ENFORCEMENT AU-
 17 THORITY.—For provisions providing for enhanced author-
 18 ity to enforce the patient protection requirements of title
 19 I under the Employee Retirement Income Security Act of
 20 1974, see section 142.

21 **SEC. 302. ENFORCEMENT FOR ECONOMIC LOSS CAUSED BY**
 22 **COVERAGE DETERMINATIONS.**

23 (a) IN GENERAL.—Section 502(c) of the Employee
 24 Retirement Income Security Act of 1974 (29 U.S.C.
 25 1132), as amended by section 142(a) of this Act, is

1 amended by redesignating paragraphs (7) and (8) as para-
2 graphs (8) and (9), respectively, and by inserting after
3 paragraph (6) the following new paragraph:

4 “(7)(A) In any case in which—

5 “(i) a coverage determination (as defined in
6 section 101(a)(2) of the Promoting Responsible
7 Managed Care Act of 1998) under a group health
8 plan (as defined in section 503(b)(8)) is not made
9 on a timely basis or is made on such a basis but is
10 not made in accordance with the terms of the plan,
11 this title, or title I of such Act, and

12 “(ii) a participant or beneficiary suffers injury
13 (including loss of life, health, or the ability to regain
14 or maintain maximum function or (in the case of a
15 child under the age of 6) development) as a result
16 of such coverage determination,

17 any person or persons who are responsible under the terms
18 of the plan for the making of such coverage determination
19 are liable to the aggrieved participant or beneficiary for
20 the amount of the economic loss suffered by the partici-
21 pant or beneficiary caused by such coverage determina-
22 tion. Any question of fact in any cause of action under
23 this paragraph shall be based on the preponderance of the
24 evidence after de novo review.

1 “(B) For purposes of subparagraph (A), the term
 2 ‘economic loss’ means any pecuniary loss (including the
 3 loss of earnings or other benefits related to employment,
 4 medical expense loss, replacement services loss, loss due
 5 to death, burial costs, and loss of business or employment
 6 opportunities) caused by the coverage determination. Such
 7 term does not include punitive damages or damages for
 8 pain and suffering, inconvenience, emotional distress,
 9 mental anguish, loss of consortium, injury to reputation,
 10 humiliation, and other nonpecuniary losses.

11 “(C) Nothing in this paragraph shall be construed as
 12 requiring exhaustion of administrative process in the case
 13 of severe bodily injury or death.”.

14 (b) EFFECTIVE DATE.—The amendments made by
 15 subsection (a) apply to coverage determinations made on
 16 or after the date of the enactment of this Act.

17 **TITLE IV—PATIENT PROTEC-**
 18 **TION STANDARDS UNDER**
 19 **THE INTERNAL REVENUE**
 20 **CODE OF 1986**

21 **SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE**
 22 **OF 1986**

23 Subchapter B of chapter 100 of the Internal Revenue
 24 Code of 1986 (as amended by section 1531(a) of the Tax-
 25 payer Relief Act of 1997) is amended—

1 (1) in the table of sections, by inserting after
 2 the item relating to section 9812 the following new
 3 item:

“Sec. 9813. Standard relating to patient protection standards.”;
 and

4 (2) by inserting after section 9812 the follow-
 5 ing:

6 **“SEC. 9813. STANDARD RELATING TO PATIENT PROTEC-**
 7 **TION STANDARDS.**

8 “A group health plan shall comply with the require-
 9 ments of title I of the Promoting Responsible Managed
 10 Care Act of 1998 (as in effect as of the date of the enact-
 11 ment of such Act), and such requirements shall be deemed
 12 to be incorporated into this section.”.

13 **TITLE V—EFFECTIVE DATES; CO-**
 14 **ORDINATION IN IMPLEMEN-**
 15 **TATION**

16 **SEC. 501. EFFECTIVE DATES.**

17 (a) GROUP HEALTH COVERAGE.—

18 (1) IN GENERAL.—Subject to paragraph (2),
 19 the amendments made by sections 201(a), 301, and
 20 401 (and title I insofar as it relates to such sections)
 21 shall apply with respect to group health plans, and
 22 health insurance coverage offered in connection with
 23 group health plans, for plan years beginning on or
 24 after January 1, 1999 (in this section referred to as

1 the “general effective date”) and also shall apply to
 2 portions of plan years occurring on and after such
 3 date.

4 (2) TREATMENT OF COLLECTIVE BARGAINING
 5 AGREEMENTS.—In the case of a group health plan
 6 maintained pursuant to 1 or more collective bargain-
 7 ing agreements between employee representatives
 8 and 1 or more employers ratified before the date of
 9 enactment of this Act, the amendments made by sec-
 10 tions 201(a), 301, and 401 (and title I insofar as it
 11 relates to such sections) shall not apply to plan
 12 years beginning before the later of—

13 (A) the date on which the last collective
 14 bargaining agreement relating to the plan ter-
 15 minates (determined without regard to any ex-
 16 tension thereof agreed to after the date of en-
 17 actment of this Act), or

18 (B) the general effective date.

19 For purposes of subparagraph (A), any plan amend-
 20 ment made pursuant to a collective bargaining
 21 agreement relating to the plan which amends the
 22 plan solely to conform to any requirement added by
 23 this Act shall not be treated as a termination of
 24 such collective bargaining agreement.

1 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—

2 The amendments made by section 202 shall apply with
3 respect to individual health insurance coverage offered,
4 sold, issued, renewed, in effect, or operated in the individ-
5 ual market on or after the general effective date.

6 **SEC. 502. COORDINATION IN IMPLEMENTATION.**

7 Section 104(1) of Health Insurance Portability and
8 Accountability Act of 1996 is amended by striking “this
9 subtitle (and the amendments made by this subtitle and
10 section 401)” and inserting “the provisions of part 7 of
11 subtitle B of title I of the Employee Retirement Income
12 Security Act of 1974, the provisions of parts A and C of
13 title XXVII of the Public Health Service Act, chapter 100
14 of the Internal Revenue Code of 1986, and title I of the
15 Promoting Responsible Managed Care Act of 1998”.

